SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS
OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER: 5765075
PAGE 1 OF 21

2. CONTRACT NO.: 75N92020C00006
3. AWARD/EFFECTIVE DATE:
4. ORDER NUMBER:
5. SOLICITATION NUMBER:
6. SOLICITATION ISSUE DATE:

7. **FOR SOLICITATION INFORMATION CALL:** a. NAME: Shirley Ruiz-Lundgren
b. TELEPHONE NUMBER *(No collect calls)*: 301-827-7529
8. OFFER DUE DATE/LOCAL TIME:

9. ISSUED BY CODE IO-NHLBI

National Institutes of Health
National Heart, Lung, and Blood
Institutes
Bethesda MD 20892-7511

10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:
☐ SMALL BUSINESS
☐ HUBZONE SMALL BUSINESS
☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
☐ EDWOSB
☐ 8(A)
NAICS: 621511
SIZE STANDARD: $32.5

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED ☒ SEE SCHEDULE
12. DISCOUNT TERMS:
☐ 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)
13b. RATING:
14. METHOD OF SOLICITATION ☐ RFQ ☐ IFB ☐ RFP

15. DELIVER TO CODE BLDG 1, BETHMC

BLDG 1, BETHMC
James A. Shannon Building,
BLDG 1,
1 Center Drive
N/A
Bethesda MD 20892

16. ADMINISTERED BY CODE ADM-NHLBI

National Institutes of Health
National Heart, Lung and Blood
Institute
Bethesda MD 20892-7511

17a. CONTRACTOR/OFFEROR CODE 079920413 FACILITY CODE

HELIX OPCO, LLC
Attn: James Lu
101 S Ellsworth Ave
STE 350
San Mateo CA 94401

TELEPHONE NO. 832-744-7129

18a. PAYMENT WILL BE MADE BY CODE NHLBI INV-BR-B

NHLBI Branch B Invoice
2115 East Jefferson St, MSC 8500
Room 4B-432
Bethesda MD 20892-8500

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER
18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) Project #6435: Reproducible clinical test system for SARS-CoV-2 tests using amplicon sequencing This Letter Contract forms a preliminary understanding between Helix OpCo, LLC (Helix) and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) to increase the testing capacity of high throughput labs by scaling up late stage				

(Use Reverse and/or Attach Additional Sheets as Necessary)

25. ACCOUNTING AND APPROPRIATION DATA: See schedule
26. TOTAL AWARD AMOUNT *(For Govt. Use Only)*: $13,022,500.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.
☐ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR
(b)(6)

31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)*
Shirley Ruiz-lundgren -S
Digitally signed by Shirley Ruiz-lundgren -S
Date: 2020.07.30 12:27:15 -04'00'

30b. NAME AND TITLE OF SIGNER *(Type or print)*: James Lu, Chief Scientific Officer
30c. DATE SIGNED: July 29, 2020
31b. NAME OF CONTRACTING OFFICER *(Type or print)*: Shirley Ruiz-Lundgren
31c. DATE SIGNED:

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. This Letter Contract is an Undefinitized Contract Action that will be definitized in accordance with the schedule contained herein. Period of Performance: 07/30/2020 to 07/29/2021				
1	Stage 1 Initiate Scale Up - RADx, COVID 19 Initiative Obligated Amount: (b)(4) [redacted] Delivery: 08/07/2020 Project Data: 151796-2020.100-HNA1 OD IOD IMMEDIATE OFFICE OF THE DIRECTOR-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-07/28/2020 Accounting Info: Funded: (b)(4) [redacted]	1	EA	(b)(4) [redacted]	
2	Stage 2 Regulatory Submission, Collection Kit, more - RADx - COVID 19 Initiative Obligated Amount: (b)(4) [redacted] Delivery: 09/01/2020 Continued ...	1	EA	(b)(4) [redacted]	

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED:

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32c. DATE

32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER

☐ PARTIAL ☐ FINAL

34. VOUCHER NUMBER

35. AMOUNT VERIFIED CORRECT FOR

36. PAYMENT

☐ COMPLETE ☐ PARTIAL ☐ FINAL

37. CHECK NUMBER

38. S/R ACCOUNT NUMBER

39. S/R VOUCHER NUMBER

40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT

41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

41c. DATE

42a. RECEIVED BY *(Print)*

42b. RECEIVED AT *(Location)*

42c. DATE REC'D *(YY/MM/DD)*

42d. TOTAL CONTAINERS

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75N92020C00006

NAME OF OFFEROR OR CONTRACTOR
HELIX OPCO, LLC

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Project Data: 151796-2020.100-HNA1 OD IOD IMMEDIATE OFFICE OF THE DIRECTOR-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-07/28/2020 Accounting Info: 08034620200DAD-2020-81-A100-EMHNA10000C-E-C4490-406-COVD-25235-9999-9999-9999-151796-2020.100-HNA1 OD IOD IMMEDIATE OFFICE OF THE DIRECTOR-07/28/2020-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-8046555 Funded: (b)(4)				

PART I – THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This Letter Contract forms a preliminary understanding between Helix OpCo, LLC (Helix) and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) program to increase the testing capacity of high throughput labs by scaling up late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. Issuance of this Letter Contract authorizes the Contractor to immediately begin the activities necessary to perform the requirements as identified in the Statement of Objectives covering the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public.

The scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public. The Helix technology to support this effort is an amplicon based next generation sequencing (NGS) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory nasopharyngeal (NP), anterior nares (AN) and oropharyngeal (OP) swab specimens. Using this technology, Helix will scale up testing capacity to 50,000 tests per day by (b)(4) and 100,000 tests per day by (b)(4)

This Letter Contract has been issued based on the submissions by the contractor under the RADx-ATP program, which includes the application and preliminary work file and subsequent documentation submitted during the review process. The Contractor's inability to meet the requirements as defined within this Letter Contract and proposed within the application process may result in the termination of the Letter Contract in accordance with the termination clauses contained herein.

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this Letter Contract is $13,022,500.

b. **Pricing Schedule**

Milestone	**Date**	**Description**	**Price**
1	8/7/2020	Stage 1: Initiate Scale Up/EUA Authorization of PCR	(b)(4)
2	9/1/2020	Stage 2: Regulatory Submission, Collection Kit, and 25,000/daily on PCR	

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. The parties acknowledge and agree that the situation around COVID-19 is highly dynamic, evolving rapidly, and subject to significant uncertainty. The Letter Contract is being executed on an expedited timeline to meet an urgent and compelling Government need without the benefit of prior negotiation. Thus, the parties will negotiate in good faith to ensure that the definitized contract reflects an appropriate allocation of risk and responsibility and that it is consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through this Letter Contract issuance. Until the Performance Work Statement (PWS) is finalized the Statement of Objective (SOO) will govern.

b. The parties anticipate that the definitive contract resulting from this Letter Contract will include a negotiated firm fixed price not to exceed $33,421,500.The amount of funding provided for this Letter Contract is stated in Article B.2 above, the contractor shall not incur costs in excess of this amount.

c. Commercial Item Status: The services provided by the Contractor under the Letter Contract and any definitized contract constitute commercial item services, and the terms of any definitized contract will reflect that understanding.

d. Performance Work Statement: The parties will negotiate a Performance Work Statement in the process of contract definitization to fairly reflect the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between application submission through letter contract issuance.

e. HHS reserves the right to exercise priorities and allocations authority with respect to this Letter Contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

f. The parties agree prior to negotiate further the terms of milestone payments to include in the definitized contract. In the negotiation, the parties will consider terms addressing liquidation of milestone payments.

g. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA), EUA 201717 for NGS and recently issued PCR EUA. The Contractor shall copy us on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EUA services provided under this Letter Contract constitute a commercial service to detect SARS-CoV-2.

h. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States.

i. Security and Privacy of Protected Health Information (PHI) processed under this contract: In the event the Contractor meets the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Contractor shall comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create PHI on behalf of the Contractor, the Contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the PHI. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a security or privacy breach applicable to PHI processed under this contract, in addition to following the procedures set forth in 45 C.F.R. Part 164, the Contractor shall also immediately notify the NIH via the Contracting Officer (CO) and the Contracting Officer's Representative (COR).

j. In accordance with the goals of the RADx program, the testing capabilities produced under this contract are to be sold for utilization within the U.S. and its territories.

k. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of this Letter Contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leveragre established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

l. Contractor Facilities: The Contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the Contractor to perform the deliverables and achieve the milestones in accordance with the Statement of Objectives and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment shall be arranged by Contractor at no additional cost to the Government. The laboratory must be CLIA certified and currently operating with appropriate equipment and trained staff.

m. The parties agree to address HHS Information Security and Privacy Requirements, as applicable, during definitization of the contract.

n. Letter Contract Termination: In accordance with FAR 52.212-4 (l) Termination for the Government's Convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

o. Letter Contract Termination: In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated 07/27/2020, set forth in SECTION J-List of Attachments, attached hereto and made a part of this Letter Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract award.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Reporting requirements TBD.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this Letter Contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and milestones to be achieved.
b. Inspection and acceptance will be performed as identified in the contract requirements.

SECTION F - DELIVERIES OR PERFORMANCE ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract is anticipated to be July 30, 2020 through July 29, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Letter Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule.

The deliverables or documentation shall be submitted to the Contracting Officer or designated Contracting Officer Representative (COR).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Shirley Ruiz-Lundgren
Telephone: 301-827-7529
Email: shirley.ruiz-lundgren@nih.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to:

1) direct or negotiate any changes in the Statement of Objectives or Performance Work Schedule;
2) modify or extend the period of performance;
3) change the deliverables or milestones schedule;
4) authorize reimbursement to the Contractor for any costs incurred during the performance of this Letter Contract;
5) otherwise change any terms and conditions of this Letter Contract; or
6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of this Letter Contract.

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirements shall be provided to the CO issuing this Letter Contract and the COR supporting the CO.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Olga Hartman, PhD
Telephone: 443-350-7696
Email: olga.hartman.civ@mail.mil

The COR is responsible for:

(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
(2) interpreting the Statement of Objectives or PWS and any other technical performance requirements;
(3) performing technical evaluation as required;
(4) performing technical inspections and acceptances required by this Letter Contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this contract is considered to be essential to work performance. At least 15 days prior to any changes to the individual listed below to other programs or contracts (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer.

James Lu, MD, PhD
Chief Scientific Officer
Primary Program Manager
Telephone: (b)(6)
Email: (b)(6)

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

a. The Contract Title is: RADx ATP [75N92020C00006] [Helix OpCo, LLC] Reproducible clinical test system for SARS-CoV-2 tests using amplicon sequencing
b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.
c. Invoice Instructions are attached and made part of this Letter Contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the Letter Contract or requested by the Contracting Officer.

    a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

        NHLBI Branch B Central Mailbox (NHLBIContractsBranchB@mail.nih.gov)

        NIH centralized invoice email box: invoicing@nih.gov

2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this task order is **NHLBI**.

    b. Central Point of Distribution. For the purpose of this Task Order, the Central Point of Distribution is **NHLBI Branch B Invoices**.

    c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

e. Invoice Matching Option. This Letter Contract requires a **two-way** match.

f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see Section B – PRICES/OPTION).

d. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITONAL CONTRACT CLAUSES

ARTICLE H.1. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan** – The parties agree to address the requirements of this Article during definitization of the contract, if applicable.

1. The Small Business Subcontracting Plan, dated____________is attached hereto and made a part of this Letter Contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this Letter Contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)
   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:
   April 30th October 30th
   Expiration Date of Contract
   Summary Subcontract Report (SSR)
2. Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:
   October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:
Shirley Ruiz-Lundgren shirley.ruiz-lundgren@nih.gov
Contracting Officer

ARTICLE H.2. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this Letter Contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of this Letter Contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this Letter Contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.3. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this Letter Contract in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Office of the Director, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92020C00006."

ARTICLE H.4. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office of Inspector
General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

This Letter Contract incorporates the following clauses by reference, to the extent applicable, with the same force and effect as if they were given in full text. – The parties agree to address the requirements of this Article during definitization of the contract.

a. HHSAR Clause 352.227-70, Publications and Publicity
b. FAR Clause 52.212-3, Offeror Representations and Certifications – Commercial Items (Jun 2020)
c. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
d. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
e. FAR Clause 52.204-2, Security Requirements (August 1996).
    1. Alternate I (April 1984) is not applicable to this contract.
    2. Alternate II (April 1984) is not applicable to this contract.
f. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
g. FAR Clause 52.204-13, System for Award Management Maintenance
h. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
i. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
j. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
k. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
l. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
m. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).
n. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
o. FAR Clause 52.224-2, Privacy Act (April 1984).
p. FAR Clause 52.227-14, Rights in Data - General (May 2014).
q. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).
r. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors

ARTICLE I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This Letter Contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this Letter Contract by signing One Copy of the contract and returning them to the Contracting Officer not later than July 30, 2020, 12:00PM Eastern. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this Letter Contract, the Contractor is not authorized to make expenditures or incur obligations exceeding **$13,022,500.00** dollars.

(b) The maximum amount for which the Government shall be liable if this Letter Contract is terminated is **$13,022,500.00** dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Firm Fixed Price (FFP) definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Firm Fixed Price proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) The schedule for definitizing this contract is as follows:

Definitization Schedule	Date
Letter Contract Post Award Kick Off meeting	07/31/2020
Contractor Technical and Revised Price Proposal Submittal, to include subcontracting plans, if applicable	08/07/2020
Request Other than certified cost or pricing data	08/14/2020
Project Officer's Technical Questionnaire/Technical Evaluation & Review	08/17/2020
Negotiations Start	08/18/2020
Definitization of Letter Contract	09/01/2020

(c) If agreement on a definitive contract to supersede this Letter Contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of this Letter Contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, this Letter Contract shall be governed by-
  (i) All clauses required by the FAR on the date of execution of this Letter Contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);
  (ii) All clauses required by law as of the date of the Contracting Officer's determination; and
  (iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this Letter Contract shall continue in effect, except those that by their nature apply only to a Letter Contract.

4. **FAR Clause 52.204-21, Basic Safeguarding of Covered Contractor Information Systems** (Jun 2016)

(a) Definitions. As used in this clause–

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public websites) or simple transactional information, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

5. **FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items** (Jul 2020)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this Letter Contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: [*Contracting Officer check as appropriate*.] – The parties agree to address the requirements of this Article during definization of the contract.

__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUNE 2020), with *Alternate I* (OCT 1995) (41U.S.C.4704 and 10 U.S.C. 2402).
__ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509)).
__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
__ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).
__ (5) [Reserved].

__ (6) 52.204-14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).
__ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).
__ (10) [Reserved].
__ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).
    __ (ii) Alternate I (MAR 2020) of 52.219-3.
__ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
    __ (ii) Alternate I (Mar 2020) of 52.219-4.
__ (13) [Reserved]
__ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-6 .
__ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-7.
__ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
__ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
    __ (ii) Alternate I (Nov 2016) of 52.219-9.
    __ (iii) Alternate II (Nov 2016) of 52.219-9.
    __ (iv)Alternate III (Jun 2020) of 52.219-9.
    __ (v)AlteRNATE IV (JUN 2020) OF 52.219-9
__ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
    __ (ii) Alternate I (MAR 2020) of 52.219-13.
__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) (15 U.S.C. 657f).
__ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).
__ (ii) Alternate I (MAR 2020) of 52.219-28.
__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).
__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).
__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C. 644(r)).
__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).
__ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).
__ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020)

(E.O.13126)
__ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
__ (30) (i) 52.222-26, Equal Opportunity (SEP 2016) (E.O.11246).
  __ (ii) Alternate I (FEB 1999) of 52.222-26.
__ (31) (i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
  __ (ii) Alternate I (JUL 2014) of 52.222-35.
__ (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
  __ (ii) Alternate I (JUL 2014) of 52.222-36.
__ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).
__ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
__ (35) (i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).
  __ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
__ (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
__ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
  __ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)
__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).
__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).
__ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).
  __ (ii) Alternate I (OCT 2015) of 52.223-13.
__ (41) (i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).
  __ (ii) Alternate I (Jun2014) of 52.223-14.
__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).
__ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).
  __ (ii) Alternate I (JUN 2014) of 52.223-16.
__ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).
__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).
__ (47) (i) 52.224-3 Privacy Training (JAN 2017) (5 U.S.C. 552 a).
  __ (ii) Alternate I (JAN 2017) of 52.224-3.
__ (48) 52.225-1, Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).
__ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

__ (ii) Alternate I (May 2014) of 52.225-3.
__ (iii) Alternate II (May 2014) of 52.225-3.
__ (iv) Alternate III (MAY 2014) of 52.225-3.
__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
__ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).
__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).
__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).
__ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).
__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
__ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
__ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).
__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
__ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).
__ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).
__ (ii) Alternate I (Apr 2003) of 52.247-64.
__ (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[*Contracting Officer check as appropriate.*]

__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).
__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).
__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).
__ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).
__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this Letter Contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this Letter Contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this Letter Contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this Letter Contract. If this Letter Contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this Letter Contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).
(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).
(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
(v) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(vi) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
(vii) 52.222-26, Equal Opportunity (SEP 2015) (E.O.11246).

(viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
(x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
(xii) 52.222-41, Service Contract Labor Standards (Aug2018) (41 U.S.C. chapter 67).
(xiii) (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O 13627).
(B) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).
(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY2014) (41 U.S.C. chapter 67).
(xvi) 52.222-54, Employment Eligibility Verification (OCT 2015) (E.O. 12989).
(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).
(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).
(xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
(B) Alternate I (Jan 2017) of 52.224-3.
(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J LIST OF ATTACHMENTS

1. Statement of Objectives
2. Helix Contract Deliverables

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER: 5766140

PAGE 1 OF 22

2. CONTRACT NO.: 75N92020C00007

3. AWARD/ EFFECTIVE DATE:

4. ORDER NUMBER:

5. SOLICITATION NUMBER:

6. SOLICITATION ISSUE DATE:

7. FOR SOLICITATION INFORMATION CALL: a. NAME: SHIRLEY RUIZ-LUNDGREN b. TELEPHONE NUMBER *(No collect calls)*: +1 301 827 7529

8. OFFER DUE DATE/LOCAL TIME:

9. ISSUED BY CODE NHLBI

National Institutes of Health
National Heart, Lung, and Blood Institute
Bethesda, MD 20892-7511

10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:

☐ SMALL BUSINESS
☐ HUBZONE SMALL BUSINESS
☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
☐ EDWOSB
☐ 8(A)

NAICS: 621511

SIZE STANDARD: $35.0

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED ☒ SEE SCHEDULE

12. DISCOUNT TERMS

☐ 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

13b. RATING

14. METHOD OF SOLICITATION ☐ RFQ ☐ IFB ☐ RFP

15. DELIVER TO CODE

Multiple Destinations

16. ADMINISTERED BY CODE NHLBI

National Institutes of Health
National Heart, Lung, and Blood Institute
Bethesda, MD 20892-7511

17a. CONTRACTOR/ OFFEROR CODE FACILITY CODE

GINKGO BIOWORKS, INC.:1224133
27 DRYDOCK AVENUE
FLOOR 8
BOSTON MA 022102413

TELEPHONE NO. –

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY CODE 2115 E JEFFERSON

2115 E Jefferson St
MSC 8500 Suite 4B 432
Bethesda, MD 20892-8500

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Rapid Acceleration of Diagnostics Advanced Technology Platform(RADx-ATP) Project #6381: High-Throughput Next Generation Sequencing based Molecular Diagnostic for SARS-CoV-2. This Letter Contract forms a preliminary understanding between Ginkgo Bioworks Inc. (Ginkgo)and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Advanced Technology Platforms(RADx-ATP)program to increase the testing capacity of high throughput labs by				

(Use Reverse and/or Attach Additional Sheets as Necessary)

25. ACCOUNTING AND APPROPRIATION DATA

26. TOTAL AWARD AMOUNT *(For Govt. Use Only)*: $6,574,473.60

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☒ ARE ☐ ARE NOT ATTACHED.

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR: (b)(6)

31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)*: Shirley Ruiz-lundgren -S Digitally signed by Shirley Ruiz-lundgren -S Date: 2020.07.30 12:49:42 -04'00'

30b. NAME AND TITLE OF SIGNER *(Type or print)*: Reshma Shetty, President, COO

30c. DATE SIGNED: 07 / 30 / 2020

31b. NAME OF CONTRACTING OFFICER *(Type or print)*: SHIRLEY RUIZ-LUNDGREN

31c. DATE SIGNED:

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)
Prescribed by GSA - FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	scaling up late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. This Letter Contract is an Undefinitized Contract Action that will be definitized in accordance with the schedule contained herein. Period of Performance: 07/30/2020 to 07/29/2021				
1	Task 1: Program Risk Management Obligated Amount: (b)(4) Delivery To: Rm 126 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 07/29/2021 Amount: (b)(4)				(b)(4)
2	Phase 1: Emergency Use Authorized Lab & Operational Capacity of 320-960 tests/day Obligated Amount: (b)(4) Delivery To: Rm 126 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 08/12/2020 Amount: (b)(4) Continued ...				(b)(4)

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: ____________

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32c. DATE

32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER

☐ PARTIAL ☐ FINAL

34. VOUCHER NUMBER

35. AMOUNT VERIFIED CORRECT FOR

36. PAYMENT

☐ COMPLETE ☐ PARTIAL ☐ FINAL

37. CHECK NUMBER

38. S/R ACCOUNT NUMBER

39. S/R VOUCHER NUMBER

40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT

41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

41c. DATE

42a. RECEIVED BY *(Print)*

42b. RECEIVED AT *(Location)*

42c. DATE REC'D *(YY/MM/DD)*

42d. TOTAL CONTAINERS

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75N92020C00007	PAGE 3 OF 22

NAME OF OFFEROR OR CONTRACTOR
GINKGO BIOWORKS, INC.:1224133

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
3	Phase 2: Emergency Use Authorized Lab & Operational Capacity of 960-1440 tests/day Obligated Amount: (b)(4) Delivery To: Rm 126 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 08/31/2020 Amount: (b)(4)				(b)(4)

PART I – THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This Letter Contract forms a preliminary understanding between **Ginkgo Bioworks, Inc. (Ginkgo)** and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) program to increase the testing capacity of high throughput labs by scaling up late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. Issuance of this Letter Contract authorizes the Contractor to immediately begin the activities necessary to perform the requirements as identified in the Statement of Objectives covering the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public.

The scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public. The Ginkgo technology to support this effort is to use Next Generation Sequencing (NGS) technology (b)(4)

(b)(4)

This Letter Contract has been issued based on the submissions by the contractor under the RADx-ATP program, which includes the application and preliminary work file and subsequent documentation submitted during the review process. The Contractor's inability to meet the requirements as defined within this Letter Contract and proposed within the application process may result in the termination of the Letter Contract in accordance with the termination clauses contained herein.

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this Letter Contract is $6,574,473.60.

b. Pricing Schedule			
Milestone	**Date**	**Description**	**Price**
(b)(4)			(b)(4)

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. The parties acknowledge and agree that the situation around COVID-19 is highly dynamic, evolving rapidly, and subject to significant uncertainty. The Letter Contract is being executed on an expedited timeline to meet an urgent and compelling government need without the benefit of prior negotiation. Thus, the parties will negotiate in good faith to ensure that the definitized contract reflects an appropriate allocation of risk and responsibility and that it is consistent with the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance. Until the Performance Work Statement (PWS) is finalized the Statement of Objective (SOO) will govern.

b. The parties anticipate that the definitive contract resulting from this Letter Contract will include a negotiated firm fixed price not to exceed $40,473,831.60. The amount of funding provided for this Letter Contract is stated in Article B.2 above, the contractor shall not incur costs in excess of this amount.

c. Commercial Item Status: The services provided by the Contractor under the Letter Contract and any definitized contract constitute commercial item services, and the terms of any definitized contract will reflect that understanding.

d. Performance Work Statement: The parties will negotiate the Performance Work Statement in the process of contract definitization to fairly reflect the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between application submission through letter contract issuance.

e. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

f. The parties agree prior to negotiate further the terms of milestone payments to include in the definitized contract. In the negotiation, the parties will consider terms addressing liquidation of milestone payments.

g. (b)(4)

h. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States.

i. Security and Privacy of Protected Health Information (PHI) processed under this contract: In the event the Contractor meets the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The contractor shall therefore comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO)and the Contracting Officer's Representative (COR).

j. In accordance with the goals of the RADx program, the testing capabilities produced under this contract are to be for utilization within the U.S. and its territories.

k. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of this Letter Contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

l. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to perform the deliverables and achieve the milestones in accordance with the Statement of Objectives and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment shall be arranged by contractor at no additional cost to the Government.

m. The parties agree to address HHS Information Security and Privacy Requirements, as applicable, during definitization of the contract.

n. Letter Contract Termination: In accordance with FAR 52.212-4 (l) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

o. Letter Contract Termination: In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 27, 2020, set forth in SECTION J-List of Attachments, attached hereto and made a part of this Leter Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contractaward.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Reporting requirements TBD.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and the milestones to be achieved.
b. Inspection and acceptance will be performed as identified in the contract requirements.

SECTION F - DELIVERIES OR PERFORMANCE ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract is anticipated to be July 30, 2020 through July 29, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Letter Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule.

The deliverables or documentation shall be submitted to the Contracting Officer or designated Contracting Officer Representative (COR).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Shirley Ruiz-Lundgren
Telephone: 301-827-7529
Email: shirley.ruiz-lundgren@nih.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to:

1) direct or negotiate any changes in the Satement of Objectives or Performance Work Statement;
2) modify or extend the period of performance;
3) change the deliverables or milestones schedule;
4) authorize reimbursement to the Contractor for any costs incurred during the performance of this Letter Contract;
5) otherwise change any terms and conditions of this Letter Contract; or
6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of this Letter Contract.

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing this Letter Contract and the COR supporting the CO.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Olga Hartman, PhD
Telephone: 443-350-7696
Email: olga.hartman.civ@mail.mil

The COR is responsible for:

(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
(2) interpreting the Statement of Objectives and any other technical performance requirements;
(3) performing technical evaluation as required;
(4) performing technical inspections and acceptances required by this Letter Contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this task order is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or task orders (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this task order.

The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the task order to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all task orders.

Reshma Shetty
Co-Founder and Chief Operating Officer
Primary Program Manager
Telephone: (b)(6)
Email: (b)(6)

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

a. The Contract Title is: RADx ATP [75N92020C00007] [Ginkgo Bioworks, Inc] High-Throughput Next Generation Sequencing based Molecular Diagnostic for SARS-CoV-2

b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.

c. Invoice Instructions are attached and made part of this Letter Contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in this Letter Contract or requested by the Contracting Officer.

    a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

        NHLBI Branch B Central Mailbox (NHLBIContractsBranchB@mail.nih.gov)

        NIH centralized invoice email box: invoicing@nih.gov

2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this task order is **NHLBI**.

    b. Central Point of Distribution. For the purpose of this Task Order, the Central Point of Distribution is **NHLBI Branch B Invoices**.

    c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to* *include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

e. Invoice Matching Option. This Letter Contract requires a **two-way** match.

f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see Section B – PRICES/OPTION).

d. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITIONAL CONTRACT CLAUSES

ARTICLE H.1. PRIVACY ACT, HHSAR 352.224-70 (December 2015)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations.

The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)).

The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in CFR 45 part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement:

(a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and

(b) specifies the disposition to be made of such records upon completion of contract performance.

ARTICLE H.2. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan** – The parties agree to address the requirements of this Article during definitization of the contract.

1. (b)(4)
2. (b)(4)

b. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)
   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:
   (b)(4)
   Summary Subcontract Report (SSR)
2. Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:
   (b)(4)

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

Shirley Ruiz-Lundgren shirley.ruiz-lundgren@nih.gov
Contracting Officer

ARTICLE H.3. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this Letter Contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the Letter Contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this Letter Contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.4. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this Letter Contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Director, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92020C00007.

ARTICLE H.5. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office of Inspector
General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. – The parties agree to address the requirements of this Article during definitization of the contract.

- a. HHSAR Clause 352.227-70, Publications and Publicity
- b. FAR Clause 52.212-3, Offeror Representations and Certifications – Commercial Items (Jun 2020)
- c. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
- d. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
- e. FAR Clause 52.204-2, Security Requirements (August 1996).
  1. Alternate I (April 1984) is not applicable to this contract.
  2. Alternate II (April 1984) is not applicable to this contract.
- f. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
- g. FAR Clause 52.204-13, System for Award Management Maintenance
- h. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
- i. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
- j. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
- k. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
- l. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
- m. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).
- n. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
- o. FAR Clause 52.224-2, Privacy Act (April 1984).
- p. FAR Clause 52.227-14, Rights in Data - General (May 2014).
- q. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).
- r. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors

ARTICLE I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of this Letter Contract and returning them to the Contracting Officer not later than July 30, 2020, 9:00AM EST. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this Letter Contract, the Contractor is not authorized to make expenditures or incur obligations exceeding **$6,574,473.60** dollars.

(b) The maximum amount for which the Government shall be liable if this Letter Contract is terminated is **$6,574,473.60** dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Firm Fixed Price (FFP) definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Firm Fixed Price proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) The schedule for definitizing this contract is as follows:

Definitization Schedule	Date
(b)(4)	

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of this Letter Contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, this Letter Contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this Letter Contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this Letter Contract shall continue in effect, except those that by their nature apply only to a Letter Contract.

(4) **FAR Clause 52.204-21, Basic Safeguarding of Covered Contractor Information Systems** (Jun 2016)

(a) Definitions. As used in this clause–

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public websites) or simple transactional information, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).
(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.
(iii) Verify and control/limit connections to and use of external information systems.
(iv) Control information posted or processed on publicly accessible information systems.
(v) Identify information system users, processes acting on behalf of users, or devices.
(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.
(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.
(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.
(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.
(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.
(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.
(xiv) Update malicious code protection mechanisms when new releases are available.
(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

(5) **FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items** (Jul 2020)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: [*Contracting Officer check as appropriate*.] – The parties agree to address the requirements of this Article during definization of the contract.

__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUNE 2020), with *Alternate I* (OCT 1995) (41U.S.C.4704 and 10 U.S.C. 2402).
__ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509)).
__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
__ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).
__ (5) [Reserved].
__ (6) 52.204-14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).
__ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).
__ (10) [Reserved].
__ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).
    __ (ii) Alternate I (MAR 2020) of 52.219-3.
__ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
    __ (ii) Alternate I (Mar 2020) of 52.219-4.
__ (13) [Reserved]
__ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-6 .
__ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-7.
__ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
__ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
    __ (ii) Alternate I (Nov 2016) of 52.219-9.
    __ (iii) Alternate II (Nov 2016) of 52.219-9.
    __ (iv)Alternate III (Jun 2020) of 52.219-9.
    __ (v)AlteRNATE IV (JUN 2020) OF 52.219-9
__ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
    __ (ii) Alternate I (MAR 2020) of 52.219-13.
__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) (15 U.S.C. 657f).

__ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).

__ (ii) Alternate I (MAR 2020) of 52.219-28.

__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).

__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).

__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C. 644(r)).

__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).

__ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

__ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)

__ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

__ (30) (i) 52.222-26, Equal Opportunity (SEP 2016) (E.O.11246).

__ (ii) Alternate I (FEB 1999) of 52.222-26.

__ (31) (i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

__ (ii) Alternate I (JUL 2014) of 52.222-35.

__ (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

__ (ii) Alternate I (JUL 2014) of 52.222-36.

__ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

__ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

__ (35) (i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

__ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

__ (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

__ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).

__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).

__ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

__ (ii) Alternate I (OCT 2015) of 52.223-13.

__ (41) (i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

__ (ii) Alternate I (Jun2014) of 52.223-14.

__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).

__ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT

2015) (E.O.s 13423 and 13514).

__ (ii) Alternate I (JUN 2014) of 52.223-16.

__ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).

__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).

__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).

__ (47) (i) 52.224-3 Privacy Training (JAN 2017) (5 U.S.C. 552 a).

__ (ii) Alternate I (JAN 2017) of 52.224-3.

__ (48) 52.225-1, Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).

__ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

__ (ii) Alternate I (May 2014) of 52.225-3.

__ (iii) Alternate II (May 2014) of 52.225-3.

__ (iv) Alternate III (MAY 2014) of 52.225-3.

__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

__ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).

__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).

__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).

__ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).

__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).

__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).

__ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

__ (ii) Alternate I (Apr 2003) of 52.247-64.

__ (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[*Contracting Officer check as appropriate.*]

__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).

__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).

__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).

__ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).

__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).

(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-21, Prohibition of Segregated Facilities (APR 2015).

(vii) 52.222-26, Equal Opportunity (SEP 2015) (E.O.11246).

(viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

(x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xii) 52.222-41, Service Contract Labor Standards (Aug2018) (41 U.S.C. chapter 67).

(xiii) (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O 13627).

(B) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).

(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY2014) (41 U.S.C. chapter 67).

(xvi) 52.222-54, Employment Eligibility Verification (OCT 2015) (E.O. 12989).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).

(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

(xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).

(B) Alternate I (Jan 2017) of 52.224-3.

(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J LIST OF ATTACHMENTS

1. Statement of Objectives
2. Ginkgo Contract Deliverables

Statement of Objectives

Title: Rapid Acceleration of Diagnostics (RADx) – Advanced Technology Platforms (ATP) High-Throughput Next Generation Sequencing based Molecular Diagnostic for SARS-CoV-2
Agency: National Institutes of Health (NIH)

1. Background

The National Institutes of Health (NIH), through the National Institute of Biomedical Imaging and Bioengineering (NIBIB) has a requirement to provide up to $230M across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. Rapid Acceleration of Diagnostics (RADx), is a fast-track technology development program that leverages the NIH Point-of-Care Technology Research Network (POCTRN). RADx supports novel solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. RADx is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

2. Purpose and Objectives

RADx Advanced Technology Platforms (RADx-ATP) will increase testing capacity and throughput by identifying and supporting existing and late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19, that are far enough advanced to achieve rapid scale-up or expanded geographical placement in a short amount of time. Through RADx ATP, NIH aims to increase capacity and optimize throughput for point-of-care (POC) testing platforms and high-throughput laboratories. To ensure that increased availability of advanced technology platforms are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, the Department of Defense, as well as commercial and private entities to propel technologies developed by RADx into widespread use.

The RADx-ATP program will focus on scaling up technologies, including improving existing high-throughput platforms, to increase testing (i.e. detection) performance and increase the nation's testing capacity by one million tests per day.

Specifically RADx-ATP seeks to:

- Commercialize and scale production of existing technologies that are already or near FDA authorization for SARS-CoV-2 detection.
- Facilitate the development of tests capable of differentiating SARS-CoV-2 vs. Influenza virus detection
- Establish or expand regional testing hubs, to validate and perform clinical tests.
- Identify and support the resource needs to expand testing in underserved populations.
- Accelerate the development and implementation of tests for other infectious pathogens.

(b)(4)

(b)(4) This initiative aims to increase the ability for widespread diagnostic testing of the public to enable reopening and monitoring of industrial, educational and public sectors.

3. Scope

Contracts for projects at an advanced stage of readiness (referred to as Phase Two or Work Package Two) will cover the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public. Supported by a RADx expert consulting team, NIH will provide milestone-driven financial and in-kind resources to maximally accelerate progress. NIH will closely monitor progress, assess milestone achievements, and evaluate the need for continued funding. Scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

4. Performance Objectives (Required Results)

A. (b)(4)

B.

C.

D. The laboratory must be CLIA certified and currently operating with appropriate equipment and trained staff.

E. (b)(4)

F. The contractor must make the product available for independent regulatory/validation assessment

G. (b)(4)

H. The laboratory must use commercially available laboratory equipment and reagents, and have a clear and detailed plan to address any supply chain shortage issues

I. (b)(4)

J. The contractor must have a logistics plan in place for the collection and receipt of samples (e.g. have identified and partnered with appropriate courier services to deliver samples)

K. (b)(4)

L.

M.

N. The contractor must have the ability to provide de-identified data to be shared with the NIH.
O. The contractor must provide a risk mitigation plan for each identified risk and update and inform NIH on any changes/newly identified risks in an ongoing manner.
P. The contractor will provide a Quality Control Plan that includes applicable laws, without limitation, health, safety, and environmental laws.
Q. The contractor shall promptly inform NIH of decisions about, or changes to, their facilities used in the manufacturing of the Final Product.
R. The contractor shall not make changes to Process and/or Scaled up Process without the Contracting Officer's Representative (COR) prior written consent and otherwise as provided in the Quality Control Plan.
S. The contractor must meet regularly (at least weekly) with NIH officials to update on progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion
T. When guided by the COR, the contractor must collaborate and cooperate with external organizations as needed to meet the contract goals in a manner which will not infringe contractor commercial or intellectual property rights.
U. Any imported materials must be FDA-approved for use in the US.
V. The contractor must have the ability to deploy to high-risk, underserved, hard-to-reach communities, with special focus on ease-of-use (including specimen collection mode, clear and easy to understand instructions to facilitate widespread uptake). (b)(4)
(b)(4)
W. The contractor must have a robust plan to continuously collect post-market data to support a PMA/510(k) submission, share data with NIH, update clinical validity measures, monitor differences in test results by type of specimen, collection device, user, setting, and other variables that may impact test results.

5. Contract Type

Firm Fixed Price

6. Place of Performance

The place of performance shall be the Contractor's place of performance:

Ginkgo Bioworks
23 - 27 Drydock Ave
Boston MA 02210

7. Period of Performance

The period of performance will be set for each contract awarded under RADx ATP.
The anticipated start date will be on or around July 29, 2020, for 12 months.

8. Deliverables/Delivery Schedule

See Letter Contract Attachment 2 Ginkgo Deliverables Schedule

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

HELLOSIGN

Audit Trail

TITLE	NIH RadX Letter Agreement
FILE NAME	75N92020C00...ct.docx.pdf and 2 others
DOCUMENT ID	f0460a4dd32cb61071f60d56b6d459f763714c34
AUDIT TRAIL DATE FORMAT	MM / DD / YYYY
STATUS	● Completed

Document History

SENT

VIEWED

SIGNED

COMPLETED

(b)(4)

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER: 5763962

PAGE 1 OF 22

2. CONTRACT NO.: 75N92020C00010

3. AWARD/EFFECTIVE DATE: 07/30/2020

4. ORDER NUMBER:

5. SOLICITATION NUMBER:

6. SOLICITATION ISSUE DATE:

7. FOR SOLICITATION INFORMATION CALL: a. NAME: John Lear

b. TELEPHONE NUMBER (No collect calls): 301-827-7716

8. OFFER DUE DATE/LOCAL TIME:

9. ISSUED BY CODE IO-NHLBI

National Institutes of Health
National Heart, Lung, and Blood Institutes
Bethesda MD 20892-7511

10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:

☐ SMALL BUSINESS

☐ HUBZONE SMALL BUSINESS

☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS

☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM

☐ EDWOSB

☐ 8(A)

NAICS: 334516

SIZE STANDARD: 1,000

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED ☒ SEE SCHEDULE

12. DISCOUNT TERMS

☐ 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

13b. RATING

14. METHOD OF SOLICITATION ☐ RFQ ☐ IFB ☐ RFP

15. DELIVER TO CODE

National Institute of Biomedical Imaging and Bioengineering
2 Democracy Plaza
6707 Democracy Blvd.
Bethesda MD 20892

16. ADMINISTERED BY CODE ADM-NHLBI

National Institutes of Health
National Heart, Lung and Blood Institute
Bethesda MD 20892-7511

17a. CONTRACTOR/OFFEROR CODE 036438689 FACILITY CODE

TALIS BIOMEDICAL CORPORATION
230 Constitution Dr
Menlo Park CA 940251109

TELEPHONE NO.

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY CODE NHLBI INV-BR-B

NHLBI Branch B Invoice
2115 East Jefferson St, MSC 8500
Room 4B-432
Bethesda MD 20892-8500

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	TITLE: RADx Tech - Talis Biomedical Highly Scalable SARS-CoV-2 RNA Detection in Minutes Period of Performance: 07/30/2020 to 07/29/2021				
1	Stage 1: Initiate Manufacturing Scale Up Obligated Amount: (b)(4) Project Data: Continued ...				(b)(4)

(Use Reverse and/or Attach Additional Sheets as Necessary)

25. ACCOUNTING AND APPROPRIATION DATA: See schedule

26. TOTAL AWARD AMOUNT (For Govt. Use Only): $10,100,000.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☐ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: ____ OFFER DATED ____. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR: (b)(6)

Brian Coe (Jul 29, 2020 19:23 CDT)

30b. NAME AND TITLE OF SIGNER (Type or print): Brian Coe Chief Executive Officer

30c. DATE SIGNED: Jul 29, 2020

31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER)

Allison M. Cristman -S Digitally signed by Allison M. Cristman -S Date: 2020.07.30 13:16:18 -04'00'

31b. NAME OF CONTRACTING OFFICER (Type or print): Allison M. Cristman

31c. DATE SIGNED: 07/30/2020

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)
Prescribed by GSA - FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-07/28/2020 Accounting Info: 08039820200DAD-2020-83-8100-EM81000000C-E-C4400-406-COVD-25235-9999-9999-9999-151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-07/28/2020-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-8045207 Funded: (b)(4)				
2	Stage 2: Design Verification Obligated Amount: (b)(4) Project Data: 151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-07/28/2020 Accounting Info: 08039820200DAD-2020-83-8100-EM81000000C-E-C4400-406-COVD-25235-9999-9999-9999-151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-07/28/2020-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-8045207 Funded: (b)(4) Continued ...				(b)(4)

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: ____________

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32c. DATE

32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER

☐ PARTIAL ☐ FINAL

34. VOUCHER NUMBER

35. AMOUNT VERIFIED CORRECT FOR

36. PAYMENT

☐ COMPLETE ☐ PARTIAL ☐ FINAL

37. CHECK NUMBER

38. S/R ACCOUNT NUMBER

39. S/R VOUCHER NUMBER

40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT

41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

41c. DATE

42a. RECEIVED BY *(Print)*

42b. RECEIVED AT *(Location)*

42c. DATE REC'D *(YY/MM/DD)*

42d. TOTAL CONTAINERS

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75N92020C00010	PAGE 3	OF 22

NAME OF OFFEROR OR CONTRACTOR
TALIS BIOMEDICAL CORPORATION

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
3	Stage 3: EUA Submission				
4	Stage 4: Build and Validate First Cartridge Manufacturing Line				
5	Stage 5: Validate Second and Third Manufacturing Line				

PART I – THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This Letter Contract forms a preliminary understanding between Talis Biomedical Corporation and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Tech (RADx Tech) fast track program which supports the development and commercialization of innovative technologies to significantly increase the U.S. testing capacity for SARS-CoV-2, the virus that causes COVID-19. Issuance of this Letter Contract authorizes the Contractor to immediately begin the activities necessary to perform the requirements as identified in the Statement of Objectives.

Talis Biomedical Corporation has developed a highly scalable LAMP-based testing instrument (Talis One) for SARS-CoV-2 RNA detection, suited to the protection of vulnerable and highly exposed populations (e.g. eldercare facilities, dialysis centers, cancer treatment centers, health care workers). The test is appropriate for NPS and NS sampling either by a paraprofessional or layperson, and is completely automated, employing a single-use self-contained cartridge and tabletop instrument. The scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

This Letter Contract has been issued based on the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the Point of Care Technology Research Network (POCTRN) review process. The contractor's inability to meet the requirements as defined within this letter contract and proposed within the POCTRN application process may result in the termination of the letter contract in accordance with the termination clauses contained herein.

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for the letter contract is **$10,100,000**.

Payment Schedule
[See complete breakdown in Deliverable Schedule]

Milestone	Amount
Stage 1: Initiate Manufacturing Scale Up	(b)(4)
Stage 2: Design Verification	

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. The parties acknowledge and agree that the situation around COVID-19 is highly dynamic, evolving rapidly, and subject to significant uncertainty. The Letter Contract is being executed on an expedited timeline to meet an urgent and compelling government need without the benefit of prior negotiation. Thus, the parties will negotiate in good faith to ensure that the definitized contract reflects an appropriate allocation of risk and responsibility and that it is consistent with the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through letter contract issuance. Until the Performance Work Statement

(PWS) is finalized, the Statement of Objectives (SOO) will govern.

b. The parties anticipate that the definitive contract resulting from this Letter Contract will include a negotiated firm fixed price not to exceed **$25,400,000**. Funding in the amount not to exceed **$10,100,000** is made available under this Letter Contract. The contractor shall not incur costs in excess of this amount.

c. Commercial Item Status: The services provided by the Contractor under the Letter Contract and any definitized contract constitute commercial item services, and the terms of any definitized contract will reflect that understanding.

d. Performance Work Statement: The parties will negotiate the Performance Work Statement in the process of contract definitization to fairly reflect the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between application submission through letter contract issuance.

e. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

f. The parties agree prior to negotiate further the terms of milestone payments to include in the definitized contract. In the negotiation, the parties will consider terms addressing liquidation of milestone payments.

g. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA); the Contractor shall copy the NIH Program Manager on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EAU services provided under this contract constitute a commercial service to detect SARS-CoV-2.

h. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States.

i. In accordance with the goals of the RADx program, the testing capabilities produced under this contract are to be for utilization within the U.S. and its territories.

j. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of the contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the

Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

k. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to manufacture the Final Product to Specification in accordance with the Scaled up Process and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment shall be arranged by contractor at no additional cost to the Government.

l. Letter Contract Termination: In accordance with FAR 52.212-4(l), the Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

   Note: If the contract is terminated for convenience, the contractor shall only stop work that incurs additional expense, liability, or cost to the Government.

   In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

m. Security and Privacy of Protected Health Information (PHI) processed under this contract: In the event the Contractor meets the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Contractor shall comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create PHI on behalf of the Contractor, the Contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the PHI. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a security or privacy breach applicable to PHI processed under this contract, in addition to following the procedures set forth in 45 C.F.R. Part 164, the Contractor shall also immediately notify the NIH via the Contracting Officer (CO) and the Contracting Officer's Representative (COR).

n. Information and/or Physical Security: The parties agree to address HHS Information Security and Privacy

Requirements, as applicable, during definitization of the contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 29, 2020, set forth in SECTION J – List of Attachments, attached hereto and made a part of this contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through letter contract issuance.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Reporting Requirements TBD
Placeholder: De-identified data for NIH research database

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of materials and services to be provided.
b. Inspection and acceptance will be performed utilizing the success criteria outlined in the deliverable schedule.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated delivery schedule.

The deliverables shall be submitted to the Contracting Officer or designated Contracting Officer's Representative (COR).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Allison Cristman
Telephone: 301-827-7703
Email: allison.cristman@nih.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to:

1) direct or negotiate any changes in the Statement of Objectives or Performance Work Statement;
2) modify or extend the period of performance;
3) change the delivery schedule;
4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract;
5) otherwise change any terms and conditions of this contract; or
6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract.

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing the task order and the COR supporting the CO.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Olga Hartman, Ph.D.
Phone: 443-350-7696
Email: olga.hartman.civ@mail.mil

The COR is responsible for:

(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
(2) interpreting the statement of objectives and any other technical performance requirements;
(3) performing technical evaluation as required;
(4) performing technical inspections and acceptances required by this contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this contract is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or contracts (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the contract to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all contracts.

For purposes of this article, (b)(6) will be the Primary Program Manager.

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all contract payment requests:

a. The Contract Title is: **RADx Tech – Talis Biomedical Highly Scalable SARS-CoV-2 RNA Detection in Minutes**
b. The Contract Line Items are defined within Section 20, Schedule of Supplies/Services of the Standard Form 1449.
c. Invoice Instructions are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.

    a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

        NHLBI Branch B Central Email Box: NHLBIContractsBranchB@mail.nih.gov

        NIH Centralized Invoice Email Box: invoicing@nih.gov

2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is **NHLBI**.

    b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is **NHLBI Branch B Invoices**.

    c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    e. Invoice Matching Option. This contract requires a **two-way** match.

    f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

    g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see Section B – PRICES/OPTION).

d. Inquiries regarding payment of invoices shall be directed to the designated billing office, 301-496-6088.

SECTION H - ADDITONAL CONTRACT CLAUSES

ARTICLE H.1. SUBCONTRACTING PROVISIONS

The parties agree to address the requirements of this Article during definitization of the contract.

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated TBD is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)
   Regardless of the effective date of this contract, the Report shall be due on the following

dates for the entire life of this contract:
April 30th, October 30th
Expiration Date of Contract
Summary Subcontract Report (SSR)

2. Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:
October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

Allison Cristman, Branch Chief
allison.cristman@nih.gov

ARTICLE H.2. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.3. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92020C00010."

ARTICLE H.4. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office of Inspector
General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

The parties agree to address the requirements of this Article during definitization of the contract.

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FAR Clause 52.212-3, Offeror Representations and Certifications – Commercial Items (Jun 2020)
b. FAR Clause 52.212-4, Contract Terms and Conditions – Commercial Items (Oct 2018)
c. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
d. FAR Clause 52.204-13, System for Award Management Maintenance
e. FAR Clause 52.204-18, Commercial and Government Entity Code Maintenance (July 2016)
f. FAR Clause 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
g. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015)
h. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014)
i. FAR Clause 52.222-29, Notification of Visa Denial (April 2015)
j. FAR Clause 52.224-1, Privacy Act Notification (April 1984)
k. FAR Clause 52.224-2, Privacy Act (April 1984)

l. FAR Clause 52.227-1, Authorization and Consent (June 2020)
m. FAR Clause 52.227-3, Patent Indemnity (April 1984)
n. FAR Clause 52.227-11, Patent Rights – Ownership by the Contractor (May 2014)
o. FAR Clause 52.227-14, Rights in Data - General (May 2014)
p. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007)
q. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors

ARTICLE I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of the contract and returning them to the Contracting Officer not later than **July 30, 2020**. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding **$10,100,000** dollars.

(b) The maximum amount for which the Government shall be liable if this contract is terminated is **$10,100,000** dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Firm Fixed Price (FFP) definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Firm Fixed Price proposal, including data other than certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) The schedule for definitizing this contract is:

Target date for start of negotiations: August 17, 2020
Target date for definitization: September 1, 2020

Definitization Schedule	Date
Statement of Objectives Review	July 23, 2020
Issuance of Letter Contract	July 30, 2020
Letter Contract Post Award Kick Off meeting	July 31, 2020
Contractor Technical and Revised Price	August 10, 2020

Proposal Submittal, to include Subcontracting Plans (if applicable)	
Request Other Than Certified Cost or Pricing Data	August 14, 2020
POTQ / Technical Evaluation	August 17, 2020
Negotiations Start	August 18, 2020
Definitization of Letter Contract	September 1, 2020

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract.

4. FAR Clause 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) Definitions. As used in this clause–

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public websites) or simple transactional information, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

5. **FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Jul 2020)**

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting

Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: **Selections will be made by the Contracting Officer during definitization.**

__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUNE 2020), with *Alternate I* (OCT 1995) (41U.S.C.4704 and 10 U.S.C. 2402).
__ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509)).
__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
__ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).
__ (5) [Reserved].
__ (6) 52.204-14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).
__ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).
__ (10) [Reserved].
__ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).
    __ (ii) Alternate I (MAR 2020) of 52.219-3.
__ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
    __ (ii) Alternate I (Mar 2020) of 52.219-4.
__ (13) [Reserved]
__ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-6 .
__ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-7.
__ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
__ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
    __ (ii) Alternate I (Nov 2016) of 52.219-9.
    __ (iii) Alternate II (Nov 2016) of 52.219-9.
    __ (iv)Alternate III (Jun 2020) of 52.219-9.
    __ (v)AlterNATE IV (JUN 2020) OF 52.219-9
__ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
    __ (ii) Alternate I (MAR 2020) of 52.219-13.
__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) (15 U.S.C. 657f).

__ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).

__ (ii) Alternate I (MAR 2020) of 52.219-28.

__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).

__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).

__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C. 644(r)).

__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).

__ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

__ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)

__ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

__ (30) (i) 52.222-26, Equal Opportunity (SEP 2016) (E.O.11246).

 __ (ii) Alternate I (FEB 1999) of 52.222-26.

__ (31) (i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

 __ (ii) Alternate I (JUL 2014) of 52.222-35.

__ (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

 __ (ii) Alternate I (JUL 2014) of 52.222-36.

__ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

__ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

__ (35) (i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

 __ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

__ (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

__ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

 __ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).

__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).

__ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

 __ (ii) Alternate I (OCT 2015) of 52.223-13.

__ (41) (i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

 __ (ii) Alternate I (Jun2014) of 52.223-14.

__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).

__ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT

2015) (E.O.s 13423 and 13514).

__ (ii) Alternate I (JUN 2014) of 52.223-16.

__ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).

__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).

__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).

__ (47) (i) 52.224-3 Privacy Training (JAN 2017) (5 U.S.C. 552 a).

__ (ii) Alternate I (JAN 2017) of 52.224-3.

__ (48) 52.225-1, Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).

__ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

__ (ii) Alternate I (May 2014) of 52.225-3.

__ (iii) Alternate II (May 2014) of 52.225-3.

__ (iv) Alternate III (MAY 2014) of 52.225-3.

__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

__ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).

__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).

__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).

__ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).

__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).

__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).

__ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

__ (ii) Alternate I (Apr 2003) of 52.247-64.

__ (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[*Contracting Officer check as appropriate.*]

__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).

__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).

__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).

__ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).

__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

- (iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).
- (iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
- (v) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (vi) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
- (vii) 52.222-26, Equal Opportunity (SEP 2015) (E.O.11246).
- (viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
- (ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
- (x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
- (xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
- (xii) 52.222-41, Service Contract Labor Standards (Aug2018) (41 U.S.C. chapter 67).
- (xiii) (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O 13627).
- (B) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- (xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).
- (xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY2014) (41 U.S.C. chapter 67).
- (xvi) 52.222-54, Employment Eligibility Verification (OCT 2015) (E.O. 12989).
- (xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).
- (xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).
- (xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
- (B) Alternate I (Jan 2017) of 52.224-3.
- (xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- (xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
- (xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

PART III - LIST OF DOCUMENTS AND OTHER ATTACHMENTS

SECTION J LIST OF ATTACHMENTS

1. Statement of Objectives
    a. Appendix 1 – Schedule of Deliverables, Payment Schedule

Statement of Objectives

Program Title: Rapid Acceleration of Diagnostics (RADx) – Tech
Project Title: Highly Scalable SARS-CoV-2 RNA Detection in Minutes (Talis Biomedical Corporation)
Agency: National Institute of Biomedical Imaging and Bioengineering (NIBIB) / National Institutes of Health (NIH)

1. Background

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has an open solicitation for proposals to provide up to $500 million across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. Rapid Acceleration of Diagnostics (RADx), is a fast-track technology development program that leverages the National Institutes of Health (NIH) Point-of-Care Technology Research Network (POCTRN). RADx will support novel solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. RADx is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

2. Purpose and Objectives

NIBIB is providing substantial support to accelerate the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2, the virus that causes COVID-19. NIBIB will support the full range of product development including commercialization and product distribution. The ultimate goal of the RADx program – across multiple projects/contracts – is to make millions of tests per week available to the American public, particularly those most vulnerable to and/or disproportionately impacted by COVID-19, in the late summer of 2020, and having even more tests available in time for the 2020–2021 flu season.

To meet the accelerated timelines, RADx has assembled a national network of expert technical, clinical, manufacturing, and regulatory advisors who will provide individualized assistance for project development and commercialization. Funding for projects selected for this program will be dependent on successfully meeting aggressive project milestones. NIBIB will provide financial and in-kind support to accelerate the entire product life-cycle, from design to market, for projects that meet milestones successfully. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, the Department of Defense, as well as commercial and private entities to propel technologies developed by RADx into widespread use.

The RADx program will consider innovations at all stages of readiness to circumvent current limitations to SARS-CoV-2 testing capacity, including:

- Early stage: transformative innovations based on novel testing strategies that have potential for major scale up
- Mid stage: technologies using novel testing strategies that have demonstrated capability but need further validation, regulatory approval, and scale up
- Advanced stage (RADx ATP): modification and optimization of existing SARS-CoV-2 testing approaches, including clinical laboratory tests, that can dramatically increase testing capacity. Note: This arm of the RADx program is addressed under a separate Acquisition Plan.

Design features might include technical innovations that:

- Improve analytical performance, e.g., sensitivity, specificity, dynamic range, limit of detection, reliability, accuracy, speed (time to test result) and throughput
- Enhance operational performance through, e.g., development of a patient- and user-friendly design, use of alternative sampling strategies (e.g., saliva, exhaled breath), integration with mobile-devices, designs for home-based use or strategies to overcome bottlenecks with current testing approaches
- Improve access and reduce the cost of testing.

3. Scope

RADx-Tech is a two phase program. All applications undergo an intensive week-long risk assessment by a panel of expert technical, clinical, manufacturing, and regulatory advisors. If the proposed technology meets viability metrics, projects may be selected to enter phase one.

Phase one, performed under a separate funding mechanism, consists of an accelerated research and development program in which the awardee receives both financial support and in-kind services through RADx grant funding. This outcome of this work is a fully instantiated technology ready for clinical validation, regulatory authorization, production and commercialization.

Phase two, or Work Package 2, of the program, executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

4. Performance Objectives (Required Results)

A. Contract recipients have completed major research and development efforts and are focused in phase two on completion of required clinical validation, preparation of regulatory submissions, scale-up of production capabilities, and preparation for full commercialization of their product – a testing technology. Every contract will encompass similar expectations and milestones concerned with:
   1. meeting regulatory requirements, resulting in regulatory authorization for sale and use of the test;
   2. instantiation of agreed-upon production capacity;
   3. meeting agreed-upon production goals; and
   4. implementation of an agreed-upon commercial strategy to bring the test to market in a timeframe that will impact the COVID-19 pandemic as soon as possible.

B. Contract funding in phase two is structured in order to reduce risk to the Government, and is dependent on achievement of specific milestones in the Schedule of Deliverables, according to the Payment Schedule.

C. The contractor must use a SARS-Cov-2 test with FDA Emergency Use Authorization (EUA) (or will have EUA near the time of award), indicating a combination of sensitivity, specificity, and usability appropriate to the intended use according to FDA and/or CDC guidance, as applicable.

D. The contractor must make the product available for independent regulatory/validation assessment. The independent assessor will be selected by the Government.

5. Contract Type

The contract type is Firm Fixed Price.

6. Place of Performance

The place of performance will be at the contractor's site.

7. Period of Performance

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

8. Deliverables/Delivery Schedule

See the attached Schedule of Deliverables.

9. Other Requirements

A. The contractor must meet regularly (at least weekly) with NIH officials to update on progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion. When guided by NIH officials, the contractor must be willing to collaborate and cooperate with external organizations as needed to meet the contract goals in a manner which will not infringe contractor commercial or intellectual property rights.

10. Appendices

Appendix 1 – Schedule of Deliverables

SCHEDULE OF DELIVERABLES

No.	Objective Defined	Milestone Defined	Deliverable	Success Criteria	Deliverable Due Date	Stage
1	Manufacturing plan	Manufacturing plan	All manufacturing and automation partners identified, and contracts completed.	Manufacturing contracts completed	10-Aug-20	1
2	Finalize specifications	Finalize product design; ready for formal design verification	Final product embodiment	Design freeze	10-Aug-20	1
3	Design verification	Design verification	Formal design verification process required for FDA submission complete	Design verification complete	1-Sep-20	2
4	Analytical data	Analytical data in support of EUA submission complete	Ready for testing at Emory	Two instruments shipped to Emory CORE for independent assessment	1-Sep-20	2
5	Clinical study	Clinical study	Initiate clinical study in support of EUA submission	First test performed at clinical study site	1-Sep-20	2
6	EUA submission	EUA submission	Completed clinical study	EUA testing complete and package submitted	23-Sep-20	3
7	Build and Validate First Cartridge Manufacturing Line	Manufacturing automation lines design and build begun	Automated manufacturing line designs	Construction of first automated manufacturing line underway	23-Sep-20	3
8	Instrument Inventory	Test and validate instrument inventory	Validated instruments	Validate initial instruments	23-Sep-20	3
9	Build and Validate First Cartridge Manufacturing Line	Validation of first line	Automated manufacture of cartridges	Production capacity of 330,000 cartridges per month	30-Nov-20	4
10	FDA Approval	EUA granted	FDA authorization for the proposed test	EUA-authorized SARS-CoV-2 viral RNA test	30-Nov-20	4
11	Product Launch	Product Launch	Successful product launch	Instruments and cartridges available for sale	30-Nov-20	4
12	Production scale-up, cartridges	Production scale-up, cartridges	Validate Second and Third Mfg Lines	Production capacity of 1,000,000 cartridges per month	31-Dec-20	5
13	Production scale-up, instrument	Production scale-up, instrument	Validate instrument production capacity	3,300 instruments manufactured and available for sale, or already sold	31-Dec-20	5

SCHEDULE OF DELIVERABLES

14	Risk mitigation plan for each identified risk and update NIH in a timely manner of any changes or newly identified risks.	All stages.	Risk Mitigation Plan	Timely reporting of identified risks to the Government.	Updated as needed.	1-5
15	Progress report with supporting documentation of scale-up efforts executed.	All stages.	Progress Report	Timely reporting of progress made for each stage.	Updated throughout each stage.	1-5

PAYMENT SCHEDULE

Stage	Title	Completion Date	Firm Fixed Price
1	Initiate Manufacturing Scale-Up	10-Aug-20	(b)(4)
2	Design Verification	1-Sep-20	
3	EUA Submission	23-Sep-20	
4	Build and Validate First Cartridge Manufacturing Line	30-Nov-20	
5	Validate Second and Third Manufacturing Line	31-Dec-20	
Total FFP Amount			**$ 25,400,000**

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS
OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER 5765387

PAGE 1 OF 22

2. CONTRACT NO. 75N92020C00011

3. AWARD/ EFFECTIVE DATE

4. ORDER NUMBER

5. SOLICITATION NUMBER

6. SOLICITATION ISSUE DATE

7. FOR SOLICITATION INFORMATION CALL: a. NAME

b. TELEPHONE NUMBER *(No collect calls)*

8. OFFER DUE DATE/LOCAL TIME

9. ISSUED BY CODE IO-NHLBI

National Institutes of Health
National Heart, Lung, and Blood
Institutes
Bethesda MD 20892-7511

10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:

☐ SMALL BUSINESS
☐ HUBZONE SMALL BUSINESS
☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
☐ EDWOSB
☐ 8(A)

NAICS:

SIZE STANDARD:

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED ☒ SEE SCHEDULE

12. DISCOUNT TERMS

☐ 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

13b. RATING

14. METHOD OF SOLICITATION ☐ RFQ ☐ IFB ☐ RFP

15. DELIVER TO CODE TDP, BTHOFF

TDP, BTHOFF
2 Democracy Plaza,
6707 Democracy Blvd
Bethesda MD 20817

16. ADMINISTERED BY CODE ADM-NHLBI

National Institutes of Health
National Heart, Lung and Blood
Institute
Bethesda MD 20892-7511

17a. CONTRACTOR/ OFFEROR CODE 081179621 FACILITY CODE

Mammoth Biosciences, Inc.
279 E Grand Ave Ste 400
South San Francisco CA 940804804

TELEPHONE NO.

18a. PAYMENT WILL BE MADE BY CODE NHLBI INV-BR-B

NHLBI Branch B Invoice
2115 East Jefferson St, MSC 8500
Room 4B-432
Bethesda MD 20892-8500

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	TITLE: RADx Tech - Mammoth Biosciences Detection of SARS-CoV-2 with the CRISPR-based DETECTR™ Platform Period of Performance: 07/30/2020 to 07/29/2021				
1	RADx Tech Project #2324 Mammoth - Stage 1 - Supply Vendor Agreements Obligated Amount: (b)(4) Continued ...				(b)(4)

(Use Reverse and/or Attach Additional Sheets as Necessary)

25. ACCOUNTING AND APPROPRIATION DATA
See schedule

26. TOTAL AWARD AMOUNT *(For Govt. Use Only)*
$9,150,000.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☐ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☐ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN ______ COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: ______ OFFER DATED ______. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR
(b)(6)

31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)*
Kristiane E. Cooper -S Digitally signed by Kristiane E. Cooper -S
Date: 2020.07.30 13:30:32 -04'00'

30b. NAME AND TITLE OF SIGNER *(Type or print)*
Janice Chen, CTO

30c. DATE SIGNED
July 29, 2020

31b. NAME OF CONTRACTING OFFICER *(Type or print)*
Kristiane E. Cooper

31c. DATE SIGNED

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)
Prescribed by GSA - FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Project Data: 151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-07/29/2020 Accounting Info: 08039820200DAD-2020-83-8100-EM81000000C-E-C4400-406-COVD-25235-9999-9999-9999-151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-07/29/2020-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-8045207 Funded: (b)(4) FOB: Destination				
2	RADx Tech Project #2324 Mammoth - Stage 2 - Manufacturing Design Transfer Instruments Obligated Amount: (b)(4) Project Data: 151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-07/29/2020 Accounting Info: 08039820200DAD-2020-83-8100-EM81000000C-E-C4400-406-COVD-25235-9999-9999-9999-151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-07/29/2020-25235 ALL OTHER SERVICES Continued ...				(b)(4)

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED:

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32c. DATE

32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER

☐ PARTIAL ☐ FINAL

34. VOUCHER NUMBER

35. AMOUNT VERIFIED CORRECT FOR

36. PAYMENT

☐ COMPLETE ☐ PARTIAL ☐ FINAL

37. CHECK NUMBER

38. S/R ACCOUNT NUMBER

39. S/R VOUCHER NUMBER

40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT

41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

41c. DATE

42a. RECEIVED BY *(Print)*

42b. RECEIVED AT *(Location)*

42c. DATE REC'D *(YY/MM/DD)*

42d. TOTAL CONTAINERS

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75N92020C00011	PAGE 3	OF 22

NAME OF OFFEROR OR CONTRACTOR
Mammoth Biosciences, Inc.

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	(NON-FEDERAL SOURCES)-8045207 Funded: (b)(4) FOB: Destination				
3	RADx Tech Project #2324 Mammoth - Stage 3 - Manufacturing Design - Reagents Obligated Amount: (b)(4) Project Data: 151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-07/29/2020 Accounting Info: 08039820200DAD-2020-83-8100-EM81000000C-E-C4400-406-COVD-25235-9999-9999-9999-151201-2020.300.COVID-19.DIAG-HN81 NIBIB OD OFFICE OF THE DIRECTOR-07/29/2020-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-8045207 Funded: (b)(4)				(b)(4)

PART I – THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This Letter Contract forms a preliminary understanding between Mammoth Biosciences and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics (RADx) to increase the testing capacity of high throughput labs by scaling up late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. Issuance of this Letter Contract authorizes the Contractor to immediately begin the activities necessary to perform the requirements as identified in the Statement of Objectives covering the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public.

The scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public. Mammoth Biosciences technology to support this effort is Detection of SARS-CoV-2 with the CRISPR-based DETECTR™ platform

This Letter Contract has been issued based on the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the Point of Care Technology Research Networ (POCTRN) application review process. The Contractor's inability to meet the requirements as defined within this Letter Contract and proposed within the POCTRN application process may result in the termination of the Letter Contract in accordance with the termination clauses contained herein.

ARTICLE B.2. PRICES

The total Firm Fixed Price (FFP) amount for this Letter Contract is $9,150,000.

Milestone Stage	Payment schedule	Amount
1	Report to NIH documenting supply and vendor agreements *Milestone 1.1:* (b)(4) (b)(4) *Milestone 1.2:* (b)(4) (b)(4) *Milestone 1.3:* (b)(4) (b)(4)	(b)(4)
2	Report to NIH summarizing approved instrument specifications. *Milestone 2.1:* (b)(4) (b)(4) *Milestone 2.2:* (b)(4) (b)(4)	

	Milestone 2.3: (b)(4) (b)(4)	(b)(4)
3	Report to NIH summarizing approved reagent specifications *Milestone 3.1:* (b)(4) (b)(4) *Milestone 3.2:* (b)(4) (b)(4)	
Total	Letter contract milestone payments	$9,150,000

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. The parties acknowledge and agree that the situation around COVID-19 is highly dynamic, evolving rapidly, and subject to significant uncertainty. The Letter Contract is being executed on an expedited timeline to meet an urgent and compelling government need without the benefit of prior negotiation. Thus, the parties will negotiate in good faith to ensure that the definitized contract reflects an appropriate allocation of risk and responsibility and that it is consistent with the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance. Until the Performance Work Statement (PWS) is finalized the Statement of Objective (SOO) will govern.

b. The parties anticipate that the definitive contract resulting from this Letter Contract will include a negotiated firm fixed price not to exceed $23,081,269 (see Attachment 2).

c. Funding in the amount not to exceed **$9,150,000 is made available** under this letter contract. The contractor shall not incur costs in excess of this amount

d. Commercial Item Status: The services provided by the Contractor under the Letter Contract and any definitized contract constitute commercial item services, and the terms of any definitized contract will reflect that understanding.

e. Performance Work Statement: The parties will negotiate the Performance Work Statement in the process of contract definitization to fairly reflect the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between application submission through letter contract issuance.

f. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

g. The parties agree prior to negotiate further the terms of milestone payments to include in the definitized contract. In the negotiation, the *parties will consider terms addressing liquidation of milestone payments.*

h. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA); the Contractor shall copy us on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EUA services provided under this Letter Contract constitute a commercial service to detect SARS-CoV-2.

i. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States.

j. In accordance with the goals of the RADx program, the testing capabilities produced under this contract are to to be for utilization within the U.S. and its territories.

k. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of this Letter Contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

l. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to perform the deliverables and achieve the milestones in accordance with the Statement of Objectives and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment shall be arranged by contractor at no additional cost to the Government.

m. FAR 52.212-4 (l) *Termination for the Government's convenience*. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

n. Letter Contract Termination: In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

o. **Security and Privacy of Protected Health Information (PHI) processed under this contract**: The Contractor , shall meet the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The contractor shall therefore comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO) and the Contracting Officer's Representative (COR).

p. Parties agree to establish critieria for milestones during contract definitization where applicable.

q. Security and Privacy of Protected Health Information (PHI) processed under this contract: The Contractor shall meet the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The contractor shall therefore comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO) and the Contracting Officer's Representative (COR).

r. The parties agree to address HHS Information Security and Privacy Requirements, as applicable, during definitization of the contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 27, 2020, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Letter Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Reporting requirements TBD.

Placeholder: De-identified data for NIH research database

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and the milestones to be achieved.
b. Inspection and acceptance will be performed as identified in the contract requirements.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Letter Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule.

The deliverables or documentation thereof shall be submitted to the Contracting Officer or designated Contracting Officer Representative (COR).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Kristiane E. Cooper
Telephone: 301-827-7704
Email: kristi.cooper@nih.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to:

1) direct or negotiate any changes in the Satement of Objectives or Performance Work Statement;
2) modify or extend the period of performance;
3) change the deliverables or milestones schedule;
4) authorize reimbursement to the Contractor for any costs incurred during the performance of this Letter Contract;
5) otherwise change any terms and conditions of this Letter Contract; or
6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of this Letter Contract.

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing this Letter Contract and the COR supporting the CO.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Christopher Hartshorn, PhD
Telephone: 240-781-3315
Email: christoper.hartshorn@nih.gov

The COR is responsible for:

(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
(2) interpreting the Statement of Objectives and any other technical performance requirements;
(3) performing technical evaluation as required;
(4) performing technical inspections and acceptances required by this Letter Contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this task order is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or task orders (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this task order. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the task order to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual’s effort exceed

100% across all task orders.

(b)(6)

Primary Program Manager

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

a. The Contract Title is: RADx Tech Project No. 2324 - Mammoth - Detection of SARS-CoV-2 with the CRISPR-based DETECTR$^{\mathrm{TM}}$ platform

b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.

c. Invoice Instructions are attached and made part of this Letter Contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in this Letter Contract or requested by the Contracting Officer.

    a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

        NHLBI Branch B Central Mailbox (NHLBIContractsBranchB@mail.nih.gov)

        NIH centralized invoice email box: invoicing@nih.gov

2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this task order is **NHLBI**.

    b. Central Point of Distribution. For the purpose of this Task Order, the Central Point of Distribution is **NHLBI Branch B Invoices**.

    c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor

Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

e. Invoice Matching Option. This Letter Contract requires a **two-way** match.

f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see Section B – PRICES/OPTION).

d. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITONAL CONTRACT CLAUSES

ARTICLE H.1. SUBCONTRACTING PROVISIONS

The parties agree to address the requirements of this Article during definitization of the contract.

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated____________is attached hereto and made a part of this Letter Contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this Letter Contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)
   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:
   April 30th October 30th
   Expiration Date of Contract
   Summary Subcontract Report (SSR)

2. Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:
   October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

Kristiane E. Cooper – kristi.cooper@nih.gov
Contracting Officer

ARTICLE H.2. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this Letter Contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the Letter Contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this Letter Contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.3. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this Letter Contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institutes of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92020C00011.

ARTICLE H.4. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office of Inspector
General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

The parties agree to address the requirements of this Article during definitization of the contract.

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FAR Clause 52.212-3 Offeror Representations and Certifications – Commercial Items (May 2014)
b. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
c. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
d. FAR Clause 52.204-2, Security Requirements (August 1996).
    1. Alternate I (April 1984) is not applicable to this contract.
    2. Alternate II (April 1984) is not applicable to this contract.
e. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
f. FAR Clause 52.204-13, System for Award Management Maintenance
g. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
h. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
i. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
j. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
k. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
l. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).
m. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
n. FAR Clause 52.224-2, Privacy Act (April 1984).
o. FAR Clause 52.227-1, Authorization and Consent (June 2007)
p. FAR Clause 52.227-3, Patent Indemnity (APR 1984)
q. FAR Clause 52.227-11, Patent Rights – Ownership by the Contractor (May 2014)
r. FAR Clause 52.227-14, Rights in Data - General (May 2014).
s. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).

t. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors

ARTICLE I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of this Letter Contract and returning them to the Contracting Officer not later than July 29, 5:00 EST. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this Letter Contract, the Contractor is not authorized to make expenditures or incur obligations exceeding $9,150,000 dollars.

(b) The maximum amount for which the Government shall be liable if this Letter Contract is terminated is $9,150,000 dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Firm Fixed Price (FFP) definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Firm Fixed Price proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) Date for submission of the price proposal, required pricing data and data other than certified cost or pricing data, and if required, make-or-buy and subcontracting plans:

Date for start of negotiations: 08/17/2020
Target date for definitization: 09/15/2020 or sooner

Definitization Schedule	Date
Statement of Objectives Review	07/26/2020
Issuance of Letter Contract	07/30/2020
Letter Contract Post Award Kick Off meeting	07/31/2020
Contractor Technical and Revised Price Proposal Submittal	08/10/2020
Request Other than certified cost or pricing data	08/17/2020
Project Officer's Technical Questionnaire/Technical Evaluation &Review	8/14/2020

Negotiations Start	08/17/2020
Definitization of Letter Contract	09/15/2020

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of this Letter Contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, this Letter Contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this Letter Contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this Letter Contract shall continue in effect, except those that by their nature apply only to a Letter Contract.

4. FAR Clause 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) Definitions. As used in this clause–

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public websites) or simple transactional information, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

5. **FAR 52.214-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Jul 2020)**

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

Selections will be made by the Contracting Officer during definitization.

__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUNE 2020), with *Alternate I* (OCT 1995) (41U.S.C.4704 and 10 U.S.C. 2402).
__ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509)).
__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
__ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).
__ (5) [Reserved].
__ (6) 52.204-14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).
__ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).
__ (10) [Reserved].
__ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).
    __ (ii) Alternate I (MAR 2020) of 52.219-3.
__ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
    __ (ii) Alternate I (Mar 2020) of 52.219-4.
__ (13) [Reserved]
__ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-6 .
__ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-7.
__ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
__ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
    __ (ii) Alternate I (Nov 2016) of 52.219-9.
    __ (iii) Alternate II (Nov 2016) of 52.219-9.
    __ (iv)Alternate III (Jun 2020) of 52.219-9.
    __ (v)AlterNATE IV (JUN 2020) OF 52.219-9
__ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
    __ (ii) Alternate I (MAR 2020) of 52.219-13.
__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) (15 U.S.C. 657f).
__ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).
__ (ii) Alternate I (MAR 2020) of 52.219-28.
__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged

Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).

__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).

__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C. 644(r)).

__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).

__ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

__ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)

__ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

__ (30) (i) 52.222-26, Equal Opportunity (SEP 2016) (E.O.11246).

  __ (ii) Alternate I (FEB 1999) of 52.222-26.

__ (31) (i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

  __ (ii) Alternate I (JUL 2014) of 52.222-35.

__ (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

  __ (ii) Alternate I (JUL 2014) of 52.222-36.

__ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

__ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

__ (35) (i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

  __ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

__ (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

__ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

  __ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).

__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).

__ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (OCT 2015) of 52.223-13.

__ (41) (i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (Jun2014) of 52.223-14.

__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).

__ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (JUN 2014) of 52.223-16.

__ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).

__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).
__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).
__ (47) (i) 52.224-3 Privacy Training (JAN 2017) (5 U.S.C. 552 a).
    __ (ii) Alternate I (JAN 2017) of 52.224-3.
__ (48) 52.225-1, Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).
__ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.
    __ (ii) Alternate I (May 2014) of 52.225-3.
    __ (iii) Alternate II (May 2014) of 52.225-3.
    __ (iv) Alternate III (MAY 2014) of 52.225-3.
__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
__ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).
__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).
__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).
__ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).
__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
__ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
__ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).
__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).
__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).
__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
__ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).
__ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).
    __ (ii) Alternate I (Apr 2003) of 52.247-64.
    __ (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[*Contracting Officer check as appropriate.*]

__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).
__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug

2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).
__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).
__ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).
__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).
(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).

- (iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
- (v) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (vi) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
- (vii) 52.222-26, Equal Opportunity (SEP 2015) (E.O.11246).
- (viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
- (ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
- (x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
- (xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
- (xii) 52.222-41, Service Contract Labor Standards (Aug2018) (41 U.S.C. chapter 67).
- (xiii) (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O 13627).
- (B) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
- (xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).
- (xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY2014) (41 U.S.C. chapter 67).
- (xvi) 52.222-54, Employment Eligibility Verification (OCT 2015) (E.O. 12989).
- (xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).
- (xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).
- (xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
- (B) Alternate I (Jan 2017) of 52.224-3.
- (xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- (xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
- (xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J LIST OF ATTACHMENTS

1. Statement of Objectives
2. Mileston payments for letter contract definization

Statement of Objectives

Program Title: Rapid Acceleration of Diagnostics (RADx) – Tech
Project Title: Detection of SARS-CoV-2 with the CRISPR-based DETECTR™ platform
Agency: National Institute of Biomedical Imaging and Bioengineering (NIBIB) / National Institutes of Health (NIH)

1. Background

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has an open solicitation for proposals to provide up to $500 million across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. Rapid Acceleration of Diagnostics (RADx), is a fast-track technology development program that leverages the National Institutes of Health (NIH) Point-of-Care Technology Research Network (POCTRN). RADx will support novel solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. RADx is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

2. Purpose and Objectives

NIBIB is providing substantial support to accelerate the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2, the virus that causes COVID-19. NIBIB will support the full range of product development including commercialization and product distribution. The ultimate goal of the RADx program – across multiple projects/contracts – is to make millions of tests per week available to the American public, particularly those most vulnerable to and/or disproportionately impacted by COVID-19, in the late summer of 2020, and having even more tests available in time for the 2020–2021 flu season.

To meet the accelerated timelines, RADx has assembled a national network of expert technical, clinical, manufacturing, and regulatory advisors who will provide individualized assistance for project development and commercialization. Funding for projects selected for this program will be dependent on successfully meeting aggressive project milestones. NIBIB will provide financial and in-kind support to accelerate the entire product life-cycle, from design to market, for projects that meet milestones successfully. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, the Department of Defense, as well as commercial and private entities to propel technologies developed by RADx into widespread use.

The RADx program will consider innovations at all stages of readiness to circumvent current limitations to SARS-CoV-2 testing capacity, including:

- Early stage: transformative innovations based on novel testing strategies that have potential for major scale up
- Mid stage: technologies using novel testing strategies that have demonstrated capability but need further validation, regulatory approval, and scale up
- Advanced stage (RADx ATP): modification and optimization of existing SARS-CoV-2 testing approaches, including clinical laboratory tests, that can dramatically increase testing capacity. Note: This arm of the RADx program is addressed under a separate Acquisition Plan.

Design features might include technical innovations that:

- Improve analytical performance, e.g., sensitivity, specificity, dynamic range, limit of detection, reliability, accuracy, speed (time to test result) and throughput
- Enhance operational performance through, e.g., development of a patient- and user-friendly design, use of alternative sampling strategies (e.g., saliva, exhaled breath), integration with mobile-devices, designs for home-based use or strategies to overcome bottlenecks with current testing approaches
- Improve access and reduce the cost of testing.

3. Scope

RADx-Tech is a two phase program. All applications undergo an intensive week-long risk assessment by a panel of expert technical, clinical, manufacturing, and regulatory advisors. If the proposed technology meets viability metrics, projects may be selected to enter phase one.

Phase one, performed under a separate funding mechanism, consists of an accelerated research and development program in which the awardee receives both financial support and in-kind services through RADx grant funding. This outcome of this work is a fully instantiated technology ready for clinical validation, regulatory authorization, production and commercialization.

Phase two, or Work Package 2, of the program, executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

4. Performance Objectives (Required Results)

A. Contract recipients have completed major research and development efforts and are focused in phase two on completion of required clinical validation, preparation of regulatory submissions, scale-up of production capabilities, and preparation for full commercialization of their product – a testing technology. Every contract will encompass similar expectations and milestones concerned with:
   1. meeting regulatory requirements, resulting in regulatory authorization for sale and use of the test;
   2. instantiation of agreed-upon production capacity;
   3. meeting agreed-upon production goals; and
   4. implementation of an agreed-upon commercial strategy to bring the test to market in a timeframe that will impact the COVID-19 pandemic as soon as possible.

B. Contract funding in phase two is structured in order to reduce risk to the Government, and is dependent on achievement of specific milestones in the Schedule of Deliverables, according to the Payment Schedule.

C. The contractor must use a SARS-Cov-2 test with FDA EUA (or will have EUA near the time of award), indicating a combination of sensitivity, specificity, and usability appropriate to the intended use according to FDA and/or CDC guidance, as applicable.

D. The contractor must make the product available for independent regulatory/validation assessment. The independent assessor will be selected by the Government.

E. In accordance with the goals of the RADx program, the tests/devices produced under this contract are to be sold within the U.S. and its territories.

F. The contractor must shall provide a risk mitigation plan for each identified stage and update and inform NIH on any changes/newly identified risks in an ongoing manner

5. Contract Type

The contract type is Firm Fixed Price.

6. Place of Performance

The place of performance will be at the contractor's site.

7. Period of Performance

The period of performance is anticipated to be July 30, 2020 through July 29, 2021.

8. Option for Increased Services

N/A

9. Deliverables/Delivery Schedule

NOTE: Milestones 4-7 will be are not included as part of the Letter Contract and will be included as part of contract definitization.

Deliverable Number	Deliverable	Due Date
1	Progress Report to NIH documenting supply and vendor agreements and risk mitigation plan – see 4f. *Milestone 1.1:* (b)(4) (b)(4) (b)(4) *Milestone 1.2:* (b)(4) (b)(4) *Milestone 1.3:* (b)(4) (b)(4)	(b)(4)
2	Progress Report to NIH summarizing approved instrument specifications and risk mitigation plan – see 4f. *Milestone 2.1:* (b)(4) (b)(4) *Milestone 2.2* (b)(4) (b)(4) *Milestone 2.3:* (b)(4) (b)(4) (b)(4)	(b)(4)
3	Progress Report to NIH summarizing approved reagent specifications and risk mitigation plan – see 4f. *Milestone 3.1:* (b)(4) (b)(4)	(b)(4)

	Milestone 3.2: (b)(4) (b)(4)	
4	Progress Report to NIH summarizing system verification activities *Milestone 4.1:* (b)(4) *Milestone 4.2:* (b)(4) *Milestone 4.3:* (b)(4) (b)(4) *Milestone 4.4:* (b)(4) (b)(4)	(b)(4)
5	Progress Report to NIH with final QC test result for 20 kit or large (>=10,000 test) lot and risk mitigation plan – see 4f. *Milestone 5.1:* (b)(4) (b)(4) *Milestone 5.2:* (b)(4) (b)(4) *Milestone 5.3:* (b)(4) (b)(4)	(b)(4)
6	Progress Report to NIH documenting EUA submission for symptomatic patients and risk mitigation plan – see 4f. *Milestone 6.1:* (b)(4) (b)(4) *Milestone 6.2:* (b)(4) *Milestone 6.3:* *Milestone 6.4:* (b)(4)	(b)(4)
7	Progress Report to NIH documenting EUA for asymptomatic people and risk mitigation plan – see 4f. *Milestone 7.1:* (b)(4) (b)(4) *Milestone 7.2:* (b)(4) (b)(4) *Milestone 7.3:* (b)(4) (b)(4)	(b)(4)

10. Other Requirements

A. The contractor must meet regularly (at least weekly) with NIH officials to update on progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion. When guided by NIH officials, the contractor must be willing to collaborate and cooperate with external organizations as needed to meet the contract goals in a manner which will not infringe contractor commercial or intellectual property rights.

Milestone Payment schedule for contract definitization

Milestone Stage	Payment schedule	Amount
1	Report to NIH documenting supply and vendor agreements *Milestone 1.1:* (b)(4) (b)(4) *Milestone 1.2:* (b)(4) (b)(4) *Milestone 1.3:* (b)(4) (b)(4)	(b)(4)
2	Report to NIH summarizing approved instrument specifications. *Milestone 2.1:* (b)(4) (b)(4) *Milestone 2.2:* (b)(4) (b)(4) *Milestone 2.3:* (b)(4) (b)(4)	
3	Report to NIH summarizing approved reagent specifications *Milestone 3.1:* (b)(4) (b)(4) *Milestone 3.2:* (b)(4) (b)(4)	
4	Report to NIH summarizing system verification activities *Milestone 4.1:* (b)(4) *Milestone 4.2:* (b)(4) (b)(4) *Milestone 4.3:* (b)(4) (b)(4) *Milestone 4.4:* (b)(4) (b)(4)	
5	Report to NIH with final QC test result for (b)(4)	

	Milestone 5.1: (b)(4) (b)(4) *Milestone 5.2:* (b)(4) (b)(4) *Milestone 5.3:* (b)(4) (b)(4)	(b)(4)
6	Report to NIH documenting EUA submission for symptomatic *Milestone 6.1:* (b)(4) (b)(4) *Milestone 6.2:* (b)(4) *Milestone 6.3:* *Milestone 6.4:* (b)(4)	
7	Report to NIH documenting EUA for asymptomatic people *Milestone 7.1:* (b)(4) (b)(4) *Milestone 7.2:* (b)(4) (b)(4) *Milestone 7.3:* (b)(4) (b)(4)	
Total	Includes Contract Definitization Milestones	

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER: 5765797

PAGE 1 OF 3

2. CONTRACT NO.: 75N92020C00013

3. AWARD/ EFFECTIVE DATE:

4. ORDER NUMBER:

5. SOLICITATION NUMBER:

6. SOLICITATION ISSUE DATE:

7. FOR SOLICITATION INFORMATION CALL: a. NAME: Ahmed Hassan

b. TELEPHONE NUMBER *(No collect calls)*: 301-827-7539

8. OFFER DUE DATE/LOCAL TIME:

9. ISSUED BY CODE: IO-NHLBI

National Institutes of Health
National Heart, Lung, and Blood
Institutes
Bethesda MD 20892-7511

10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:

☐ SMALL BUSINESS

☐ HUBZONE SMALL BUSINESS

☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS

☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM

☐ EDWOSB

☐ 8(A)

NAICS: 334516

SIZE STANDARD: 1,000

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED ☒ SEE SCHEDULE

12. DISCOUNT TERMS:

☐ 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

13b. RATING:

14. METHOD OF SOLICITATION ☐ RFQ ☐ IFB ☐ RFP

15. DELIVER TO CODE: BLDG 1, BETHMC

BLDG 1, BETHMC
James A. Shannon Building,
BLDG 1,
1 Center Drive
N/A
Bethesda MD 20892

16. ADMINISTERED BY CODE: ADM-NHLBI

National Institutes of Health
National Heart, Lung, and Blood
Institute
Bethesda MD 20892-7511

17a. CONTRACTOR/ OFFEROR CODE: 097020739 FACILITY CODE:

QUIDEL CORPORATION
Attn: (b)(6)
9975 Summers Ridge Road
SAN DIEGO CA 92121

TELEPHONE NO. 8585527908

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY CODE: NHLBI INV-BR-A

NHLBI Branch A Invoice
2115 East Jefferson St, MSC 8500
Room 4B-432
Bethesda MD 20892-8500

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Title: RADx ATP - Accelerated Manufacturing Scale-Up of Rapid Point-of-Care Antigen Tests for COVID-19 Diagnosis This Letter Contract forms a preliminary understanding between Quidel Corporation and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) to increase the Scale-Up for the manufacturing capacity of Sofia SARS Antigen and				

(Use Reverse and/or Attach Additional Sheets as Necessary)

25. ACCOUNTING AND APPROPRIATION DATA: See schedule

26. TOTAL AWARD AMOUNT *(For Govt. Use Only)*: $3,000,000.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☐ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: ______ OFFER DATED ______. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR: (b)(6)

31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER): Cornelius O. Moore -S

Digitally signed by Cornelius O. Moore -S
Date: 2020.07.30 11:43:17 -04'00'

30b. NAME AND TITLE OF SIGNER (Type or print): (b)(6)

30c. DATE SIGNED: 07-29-20

31b. NAME OF CONTRACTING OFFICER (Type or print): Cornelius O. Moore

31c. DATE SIGNED: 07/30/2020

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)
Prescribed by GSA - FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Sofia Influenza A+B/SARS FIAs testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. This Letter Contract is an Undefinitized Contract Action that will be definitized in accordance with the schedule contained herein. Delivery: 07/29/2021 Period of Performance: 07/30/2020 to 07/29/2021				
1	RADx- ATPadditional headcount Obligated Amount: (b)(4) Project Data: 151796-2020.100-HNA1 OD IOD IMMEDIATE OFFICE OF THE DIRECTOR-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-07/29/2020 Accounting Info: Funded: (b)(4)	1	EA	(b)(4)	
2	RADx project - Modification of Manufacturing Obligated Amount: (b)(4) Project Data: 151796-2020.100-HNA1 OD IOD IMMEDIATE OFFICE OF THE DIRECTOR-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-07/29/2020 Continued ...	1	EA	(b)(4)	

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED:

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32c. DATE

32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER

☐ PARTIAL ☐ FINAL

34. VOUCHER NUMBER

35. AMOUNT VERIFIED CORRECT FOR

36. PAYMENT

☐ COMPLETE ☐ PARTIAL ☐ FINAL

37. CHECK NUMBER

38. S/R ACCOUNT NUMBER

39. S/R VOUCHER NUMBER

40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT

41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

41c. DATE

42a. RECEIVED BY *(Print)*

42b. RECEIVED AT *(Location)*

42c. DATE REC'D *(YY/MM/DD)*

42d. TOTAL CONTAINERS

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED: 75N92020C00013

PAGE 3 OF 3

NAME OF OFFEROR OR CONTRACTOR: QUIDEL CORPORATION

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Accounting Info: 08034620200DAD-2020-81-A100-EMHNA10000C-E-C4490-406-COVD-25235-9999-9999-9999-151796-2020.100-HNA1OD IOD IMMEDIATE OFFICE OF THE DIRECTOR-07/29/2020-25235 ALL OTHER SERVICES (NON-FEDERAL SOURCES)-8046555 Funded: (b)(4)				

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This Letter Contract forms a preliminary understanding between Quidel Corporation and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) to increase the testing capacity of high throughput labs by scaling up late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. Issuance of this Letter Contract authorizes the Contractor to immediately begin the activities necessary to perform the requirements as identified in the Statement of Objectives covering the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public.

The scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

This Letter Contract has been issued based on the the submission by the contractor under the RADx-ATP program, which includes the application and preliminary work file and subsequent documentation submitted during the review process. The Contractor's inability to meet the requirements as defined within this Letter Contract and proposed within the application process may result in the termination of the Letter Contract in accordance with the termination clauses contained herein.

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this contract is $3,000,000.

Pricing Schedule				
Milestone	**Date**	**Test/Day**	**Description**	**Price**
1	8/3/2020	(b)(4)		(b)(4)
2	9/14/2020			

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. The parties acknowledge and agree that the situation around COVID-19 is highly dynamic, evolving rapidly, and subject to significant uncertainty. The Letter Contract is being executed on an expedited timeline to meet an urgent and compelling government need without the benefit of prior negotiation. Thus, the parties will negotiate in good faith to ensure that the definitized contract reflects an appropriate allocation of risk and responsibility and that it is consistent with the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance. Until the Performance Work Statement (PWS) is finalized the Statement of Objective (SOO) will govern.

b. The parties anticipate that the definitive contract resulting from this Letter Contract will include a negotiated firm fixed price not to exceed $71,000,000. The amount of funding provided for this Letter Contract is stated in Article B.2 above, the contractor shall not invoice in excess of this amount.

c. Commercial Item Status: The services provided by the Contractor under the Letter contract and any definitized contract constitute commercial item services, and the terms of any definitized contract will reflect that understanding.

d. Performance Work Statement: The parties will continue to negotiate the Performance Work Statement in the process of contract definitization to fairly reflect the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between application submission through letter contract issuance.

e. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

f. The parties agree prior to negotiate further the terms of milestone payments to include in the definitized contract. In the negotiation, the parties will consider terms addressing liquidation of milestone payments.

g. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA); the Contractor shall copy us on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EUA services provided under this Letter Contract constitute a commercial service to detect SARS-CoV-2.

h. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States.

i. In accordance with the goals of the RADx program, the testing capabilities produced under this contract are to be for utilization within the U.S. and its territories.

j. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of the contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

k. Security and Privacy of Protected Health Information (PHI) processed under this contract: The Contractor shall meet the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The contractor shall therefore comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part

160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO) and the Contracting Officer's Representative (COR).

l. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to manufacture the Final Product to Specification in accordance with the Scaled up Process and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment shall be arranged by contractor at no additional cost to the Government.

m. Letter Contract Termination: FAR 52.212-4 (l) Termination for the Government's convenience. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

   In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

n. The Contractor shall meet the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The contractor shall therefore comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the

Contracting Officer (CO) and the Contracting Officer's Representative (COR).

o. The parties agree to address HHS Information Security and Privacy Requirements, as applicable, during definitization of the contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 25, 2020, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Leter Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract award.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible." Additional reporting will be negotiated and included upon contract definitization.

Item number	Deliverable Title	Due Date
1	Risk Management Plan	8/21/2020
2	Recurring reports (inclusive of scale up progress, challenges, status of management of adequate supply chain, current production capacity)	Weekly
3	Detailed plan to address supply chain shortages and related delays, followed by updates to this plan, as appropriate	08/07/2020
4	Final plan/approach and timeline for manufacturing line modifications to meet scale-up requirements of (b)(4) Sofia SARS Antigen FIA tests per day by June 30, 2021	08/10/2020
5	Final plan/approach for rapidly deploying the product to Point-of-Care settings	08/14/2020
6	Plan to collect post-market data to support a PMA/510(k) submission; share data with NIH; update clinical validity measures; and monitor differences in test results by type of specimen, collection device, user setting, and other variables that may impact test performance/results	08/14/2020
7	Report on the plan to collect post-market data as described in 3.e	Monthly
8	Report on the submission of permits for space renovation/construction, as appropriate	08/10/2020
9	Report on the demonstration of increased capacity to (b)(4)	08/31/2020

	Sofia SARS Antigen FIA tests/day	
10	Report on the demonstrated capability for using FHIR-based APIs for standardized electronic data transmission, or a plan for implementing such a capability within two months of letter contract ratification.	08/31/2020

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and the milestones to be achieved.
b. Inspection and acceptance will be performed as identified in the contract requirements.

SECTION F - DELIVERIES OR PERFORMANCE ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this letter contract is anticipated to be July 30, 2020 through September 16, 2020. The period of performance upon contract definitizatin will be July 30, 2020 through July 29, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated delivery schedule.

The deliverables or documentation shall be submitted to the Contracting Officer or designated Contracting Officer Representative (COR).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Cornelius Moore
Telephone: 301-827-7730
Email: mooreco@mail.nih.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to:

1) direct or negotiate any changes in the statement of work;
2) modify or extend the period of performance;
3) change the delivery schedule;
4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract;

5) otherwise change any terms and conditions of this contract; or
6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract.

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing the contract and the COR supporting the CO.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Dr. Olga Hartman
Telephone: 301-496-3500
Email: olga.hartman@nih.gov

The COR is responsible for:

(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
(2) interpreting the statement of work and any other technical performance requirements;
(3) performing technical evaluation as required;
(4) performing technical inspections and acceptances required by this contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this contract is considered essential to work performance. At least 30 calendar days prior to any changes to the individual listed below to other programs or contract (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the contract to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all contract.

(b)(6)

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all contract payment requests:

a. The Contract Title is: **RADx ATP 6313 Quidel - Manufacturing Capacity Scale-Up for Sofia SARS Antigen and Sofia Influenza A+B/SARS FIAs**

b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.

c. Invoice Instructions are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

  1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.

     a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

        NHLBI Branch A Central Mailbox (NHLBIContractsBranchA@mail.nih.gov)

        NIH centralized invoice email box: invoicing@nih.gov

  2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

  3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):

     a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is **NHLBI**.

     b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is **NHLBI Branch A Invoices**.

     c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

     d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

     e. Invoice Matching Option. This contract requires a **two-way** match.

     f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see Section B – PRICES).

d. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITONAL CONTRACT CLAUSES

ARTICLE H.1. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

The parties agree to address the requirements of this Article during definitization of the contract.

1. The Small Business Subcontracting Plan, dated____________is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. **Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)
   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:
   April 30th October 30th
   Expiration Date of Contract
   Summary Subcontract Report (SSR)
2. Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:
   October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

Cornelius Moore mooreco@mail.nih.gov
Contracting Officer

ARTICLE H.2. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.3. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the Office of the Director, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92020C00013"

ARTICLE H.4. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office of Inspector
General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. The parties agree to address the requirement of this Article during definitization of the letter contract

a. HHSAR Clause 352.227-70, Publication and Publicity
b. FAR Clause 25.212-3, Offeror Representation and Certification – Commercial Items (Jun 2020)
c. FAR Clause 52.212-3, Offeror Representations and Certifications – Commercial Items (Jun 2020)
d. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
e. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
f. FAR Clause 52.204-2, Security Requirements (August 1996).
    1. Alternate I (April 1984) is not applicable to this contract.
    2. Alternate II (April 1984) is not applicable to this contract.
g. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
h. FAR Clause 52.204-13, System for Award Management Maintenance
i. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
j. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
k. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
l. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
m. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
n. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).
o. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
p. FAR Clause 52.224-2, Privacy Act (April 1984).
q. FAR Clause 52.227-14, Rights in Data - General (May 2014).
r. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).
s. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors

ARTICLE I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of the contract and returning it to the Contracting Officer not later than July 30, 2020 12:00PM Eastern. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding $3,000,000 .

(b) The maximum amount for which the Government shall be liable if this contract is terminated is $3,000,000.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Firm Fixed Price (FFP) definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Firm Fixed Price proposal, including data other than certified cost or pricing data, , in accordance with FAR 15.408, Table 15-2, supporting its proposal.

The Schedule for definitizing this contract is as follows:

Definitization Schedule	**Date**
Statement of Objectives Review	07/25/2020
Issuance of Letter Contract	07/30/2020
Letter Contract Post Award Kick Off meeting	07/31/2020
Contractor Technical and Revised Price Proposal Submittal, to include subcontracting plan if applicable	08/14/2020
Request Other than certified cost or pricing data	08/21/2020
Project Officer's Technical Questionnaire/Technical Evaluation & Review	08/25/2020
Negotiations Start	08/27/2020
Definitization of Letter Contract (Target Date)	09/16/2020

(b) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);
(ii) All clauses required by law as of the date of the Contracting Officer's determination; and
(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract.

(c) FAR Clause 52.204-21, **Basic Safeguarding of Covered Contractor Information Systems** (Jun 2016)

(a) Definitions. As used in this clause–

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public websites) or simple transactional information, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

4. **FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Jul 2020)**

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: The parties agree to address the requirements of this Article during definization of the contract.

[Contracting Officer check as appropriate]

Selections will be made by the Contracting Officer during definitization.

__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUNE 2020), with *Alternate I* (OCT 1995) (41U.S.C.4704 and 10 U.S.C. 2402).
__ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509)).
__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
__ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN

2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).
__ (5) [Reserved].
__ (6) 52.204-14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).
__ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).
__ (10) [Reserved].
__ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).
    __ (ii) Alternate I (MAR 2020) of 52.219-3.
__ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
    __ (ii) Alternate I (Mar 2020) of 52.219-4.
__ (13) [Reserved]
__ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-6 .
__ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-7.
__ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
__ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
    __ (ii) Alternate I (Nov 2016) of 52.219-9.
    __ (iii) Alternate II (Nov 2016) of 52.219-9.
    __ (iv)Alternate III (Jun 2020) of 52.219-9.
    __ (v)AlterNATE IV (JUN 2020) OF 52.219-9
__ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
    __ (ii) Alternate I (MAR 2020) of 52.219-13.
__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) (15 U.S.C. 657f).
__ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).
__ (ii) Alternate I (MAR 2020) of 52.219-28.
__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).
__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).
__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C. 644(r)).
__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).

__ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

__ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)

__ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

__ (30) (i) 52.222-26, Equal Opportunity (SEP 2016) (E.O.11246).

  __ (ii) Alternate I (FEB 1999) of 52.222-26.

__ (31) (i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

  __ (ii) Alternate I (JUL 2014) of 52.222-35.

__ (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

  __ (ii) Alternate I (JUL 2014) of 52.222-36.

__ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

__ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

__ (35) (i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

  __ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

__ (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

__ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

  __ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).

__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).

__ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (OCT 2015) of 52.223-13.

__ (41) (i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (Jun2014) of 52.223-14.

__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).

__ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (JUN 2014) of 52.223-16.

__ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).

__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).

__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).

__ (47) (i) 52.224-3 Privacy Training (JAN 2017) (5 U.S.C. 552 a).

  __ (ii) Alternate I (JAN 2017) of 52.224-3.

__ (48) 52.225-1, Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).

__ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19

U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

    __ (ii) Alternate I (May 2014) of 52.225-3.
    __ (iii) Alternate II (May 2014) of 52.225-3.
    __ (iv) Alternate III (MAY 2014) of 52.225-3.

__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

__ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).

__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).

__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).

__ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).

__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).

__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).

__ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

    __ (ii) Alternate I (Apr 2003) of 52.247-64.
    __ (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[*Contracting Officer check as appropriate.*]

__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).

__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).

__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).

__ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to

Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).
__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).
(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).
(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
(v) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
(vii) 52.222-26, Equal Opportunity (SEP 2015) (E.O.11246).
(viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
(x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
(xii) 52.222-41, Service Contract Labor Standards (Aug2018) (41 U.S.C. chapter 67).
(xiii) (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O 13627).
(B) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).
(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY2014) (41 U.S.C. chapter 67).
(xvi) 52.222-54, Employment Eligibility Verification (OCT 2015) (E.O. 12989).
(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).
(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).
(xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
(B) Alternate I (Jan 2017) of 52.224-3.
(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS SECTION J LIST OF ATTACHMENTS

1. Statement of Objectives
2. Contract Deliverables
3. Draft Performance Work Statement

Statement of Objectives

Title: RADx ATP - Accelerated Manufacturing Scale-Up of Rapid Point-of-Care Antigen Tests for COVID-19 Diagnosis
Agency: National Institutes of Health (NIH)

1. Background

The National Institutes of Health (NIH), through the National Institute of Biomedical Imaging and Bioengineering (NIBIB) has a requirement which will provide up to $230M across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. Rapid Acceleration of Diagnostics (RADx), is a fast-track technology development program that leverages the NIH Point-of-Care Technology Research Network (POCTRN). RADx will support novel solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. RADx is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

2. Purpose and Objectives

RADx Advanced Technology Platforms (RADx-ATP) will increase testing capacity and throughput by identifying and supporting existing and late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19, that are far enough advanced to achieve rapid scale-up and/or expanded geographical placement in a short amount of time. Through RADx ATP, NIH aims to increase capacity and optimize throughput for point-of-care (POC) testing platforms and high-throughput laboratories. To ensure that increased availability of advanced technology platforms are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, the Department of Defense, as well as commercial and private entities to propel technologies developed by RADx into widespread use.

The RADx-ATP program will focus on scaling up technologies, including improving existing point of care and high-throughput platforms, to increase testing (i.e. detection) performance and increase the nation's testing capacity by one million tests per day.

Specifically RADx-ATP seeks to:

- Commercialize and scale production of existing technologies that are already or near FDA authorization for SARS-CoV-2 detection.
- Establish or expand regional testing hubs, to validate and perform clinical tests.
- Identify and support the resource needs to expand testing in underserved populations.
- Facilitate the development of tests capable of differentiating SARS-CoV-2 vs. Influenza virus detection.
- Accelerate the development and implementation of tests for other infectious

pathogens.

For RADx-ATP-funded Point-of-Care test providers, the key objectives include the ability to manufacture between 20-000 and 100,000 SARS-CoV-2 tests/day by September 1st, 2020; the ability to obtain and maintain required regulatory approvals/EUAs; the ability to scale up production and facilities to meet additional demand; ability to deploy testing in underserved, hard-to-reach communities; existing or planned (within 12 months) capacity for using FHIR-based APIs to electronically transmit data; development and execution of a robust plan to continuously collect post-market data to support a PMA/510(k) submission, share data with the NIH, and monitor variables that may impact test results; and competitive cost per test. This initiative aims to increase the ability for widespread diagnostic testing of the public to enable reopening and monitoring of industrial, educational and public sectors.

3. Scope

Funding for projects at an advanced stage of readiness (referred to as Phase Two or Work Package Two) will cover the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public. Supported by a RADx expert consulting team, NIH will provide milestone-driven financial and in-kind resources to maximally accelerate progress. NIH will closely monitor progress, assess milestone achievements, and evaluate the need for continued funding. Scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled-up capacity to the U.S. public.

4. Performance Objectives (Required Results)

- The contractor must have the capacity to scale production to between (b)(4) units of Sofia SARS Antigen FIA tests (hereto "product") per day by June 30, 2021, in accordance with the deliverables schedule defined below.
- The product must have and maintain a minimum of 90% sensitivity and 95% specificity.
- The contractor must share all FDA correspondence (to and from the FDA) regarding the regulatory submission and feedback of the product and the Sofia Influenza A+B/SARS FIA test, and invite the NIH to attend meetings with FDA regarding the product and the Sofia Influenza A+B/SARS FIA test.
- The contractor must make the product and other tests that concurrently detect Influenza A&B available for independent regulatory/validation assessment.
- The contractor must provide within two weeks a deployment/placement strategy for rapidly deploying the product to Point-of-Care settings. The contractor must provide updates to the deployment/placement strategy as needed to accommodate increased output and/or changes in demand.
- The contractor must, within two weeks of the award of the letter contract, provide a detailed plan to address supply chain shortage issues and related delays, and must provide updates to this plan, as appropriate.
- The contractor must prove existing capability for using FHIR-based APIs for standardized

electronic data transmission within one month of the ratification of the letter contract. If such capability is lacking, the contractor must, within one month of award of the letter contract, present a plan for implementing such capability within two months of letter contract ratification.

- The contractor should have the ability to test concurrently for Influenza A&B.
- The contractor must have the ability to (b)(4) (b)(4) with special focus on ease-of-use (including specimen collection mode, clear and easy to understand instructions to facilitate widespread uptake).
- The contractor must, within two weeks of award of the letter contract, submit a robust plan to continuously collect post-market data to support a PMA/510(k) submission; share data with NIH; update clinical validity measures; and monitor differences in test results by type of specimen, collection device, user, setting, and other variables that may impact test results.
- The contractor must, within three weeks of award of the letter contract, provide a risk mitigation plan for each identified risk and update and inform NIH on any changes/newly identified risks in an ongoing manner.
- The contractor must meet regularly (at least weekly) with NIH officials to update on progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion.
- When guided by NIH officials, the contractor must be willing to collaborate and cooperate with external organizations as needed to meet the contract goals in a manner which will not infringe contractor commercial or intellectual property rights.
- Any imported materials must be FDA-approved for use in the US.
- In consideration for the investment in manufacturing scale-up, the contractor must make available between (b)(4) Sofia SARS FIA Antigen tests and (b)(4) Sofia/Sofia2 Analyzers during the period of performance.

5. Contract Type

Firm Fixed Price

6. Place of Performance

Quidel Corporation
9975 Summers Ridge Rd
San Diego, CA, 92121-2997
UNITED STATES

7. Period of Performance

The period of performance is anticipated to be July 30, 2020 – July 29, 2021.

8. Deliverables/Delivery Schedule

Deliverables will be developed specific to each contract awarded. Below is an example of the types of categories of deliverables that would be provided under RADx ATP contracts.

Task No.	Deliverable Title	Due Date
1	**Program Management**	
1.a	Risk Management Plan	8/21/20
1.b	Recurring reports (inclusive of scale up progress, challenges, status of management of adequate supply chain, current production capacity)	weekly
1.c	Detailed plan to address supply chain shortages and related delays, followed by updates to this plan, as appropriate	8/14/20, updated as necessary
2	**Scale-Up and Deployment Plan**	
2.a	Final plan/approach and timeline for manufacturing line modifications to meet scale-up requirements of (b)(4) Sofia SARS Antigen FIA tests per day by June 30, 2021	8/10/20
2.b	Hire and train personnel to support scale up plan	According to plan in 2.a
2.c	Final plan/approach for rapidly deploying the product to Point-of-Care settings	8/14/20
3	**Regulatory and external testing**	
3.c	Report on the results of clinical/EUA validation studies of the combined Sofia Influenza A+B/SARS FIA test	10/31/20
3.d	Documentation of regulatory approval for combined Sofia Influenza A+B/SARS FIA test	11/30/20
3.e	Plan to collect post-market data to support a PMA/510(k) submission; share data with NIH; update clinical validity measures; and monitor differences in test results by type of specimen, collection device, user setting, and other variables that may impact test performance/results	8/14/20
3.f	Report on the plan to collect post-market data as described in 3.e	monthly
4	**Space renovation/construction and Manufacturing**	
4.a	Report on the submission of permits for space renovation/construction, as appropriate	8/10/20
4.b	Documentation of completed and passed inspections for renovated/constructed space, as appropriate	According to plan in 2.a
4.c	Final engineering drawings and environmental control specifications completed for renovated/constructed space	According to plan in 2.a
4.d	Quotes from vendors and documentation of orders for equipment for additional/modified production lines	According to plan in 2.a
4.e	Report of completed space renovation and/or construction, and installation of equipment for increasing production capacity	According to plan in 2.a
4.f	Report on the completion of debugging, validation and safety studies of new equipment/assembly/production lines; implement a quality management system	According to plan in 2.a

5	**Demonstration of Scaled Manufacturing Production**	
5.a	Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	8/31/20
5.b	Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	12/31/20
5.c	Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	3/31/21
5.d	Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	5/15/21
5.e	Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	6/30/21
5.f	Report on the demonstration of increased capacity to (b)(4) Sofia Analyzers per month	12/31/20
6	Report on the demonstrated capability for using FHIR-based APIs for standardized electronic data transmission, or a plan for implementing such a capability within two months of letter contract ratification.	8/31/20
7	Sustained supply chain and production capacity plan for the Sofia SARS Antigen FIA test and Sofia Analyzer	12/31/21

9. Other Requirements

1) Data Sharing: NIH policy promotes data sharing to allow scientists to expedite the translation of research results into products and procedures to improve human health. Sharing data reinforces open scientific inquiry, encourages diversity of analysis and opinion, promotes new research, makes possible the testing of new or alternative hypotheses and methods of analysis, supports studies on data collection methods and measurement, facilitates the education of new researchers, enables the exploration of topics not envisioned by the initial investigators, and permits the creation of new datasets when data from multiple sources are combined.

No.	Objective Defined	Milestone Defined	Deliverable	Success Criteria	Deliverable Due Date
1	Risk awareness and management	Risk mitigation plan	1a. Risk mitigation plan	Provide to NIH a thorough list of identified risks plus details on mitigation strategies.	8/5/2020
2	Recurring progress reports	Weekly progress report	1b. weekly reports	Meetings and/or documents submitted to the NIH to update progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion.	weekly
3	Supply chain management	Supply chain management plan	1.c Detailed plan to address supply chain shortages and related delays; updates to this plan as appropriate	A plan to manage adequate supply of consumable, reagents, and other equipment over the course of the scale up plan. The plan should clearly identify the consumable/equipment name/category, specifications, manufacturer, catalog number, quantity needed by critical dates, possible substitutions, existing or possible solution for obtaining the needed supply	8/14/2020
4	Scale-up plan	Final plan/approach and timeline for manufacturing modifications	2.a Final plan/approach and timeline for manufacturing line modifications to meet scale-up requirements of (b)(4) Sofia SARS Antigen FIA tests per day by (b)(4)	Detailed plan with the final approach to renovations/construction to meet the scale-up requirements, inclusive of a timeline for developing engineering diagrams; defining environmental control specifications; obtaining permits and inspections required; obtaining quotes from vendors for equipment; placing orders; installation of equipment; space renovation/construction; debugging, validation and safety studies for the new/retrofitting production and assembly lines; and implementation of a quality management system	8/5/2020
5	Scale-up plan	Hire and train personnel	2.b Hire and train personnel	Labor resources in place to carry out the scale-up plan and demonstration of increased	according to timeline in deliverable 2.a
6	Deployment plan	Deployment plan	2.c Final plan/approach for rapidly deploying the product to Point-of-Care settings	Clear description of the plan and process to rapidly deploy the product to point-of-care settings (b)(4) (b)(4)	8/14/2020
####	Regulatory and external testing	Clinical/EUA validation studies of the combined Sofia Influenza A+B/SARS FIA test	3.c Report on the results of clinical/EUA validation studies of the combined Sofia Influenza A+B/SARS FIA test	Report on the results of the clinical study that includes sample size and performance metrics met for EUA submission to FDA	10/31/2020
####	Regulatory and external testing	Regulatory approval for combined Sofia Influenza A+B/SARS FIA test	3.d Documentation of regulatory approval for combined Sofia Influenza A+B/SARS FIA test	FDA EUA for the combined Sofia Influenza A+B/SARS FIA test	11/30/2020
	Regulatory and external testing	Plan for longer term data collection and evaluation	3.e Plan to collect post-market data to support a PMA/510(k) submission; share data with NIH; update clinical validity measures; and monitor differences in test results by type of specimen, collection device, user setting, and other variables that may impact test performance/results	Data collection in support of a submission toward a PMA/510(k) from the FDA; sharing de-identified data according to a plan agreed upon with NIH; continuous evaluation of variables that may impact test performance (e.g. type of specimen, collection device, user setting)	8/14/2020
	Regulatory and external testing	Implementation of the plan for longer term data collection and evaluation	3.f Report on the plan to collect post-market data as described in 3.e	Written report on the implementation of the plan to collect post-market data as described in 3.e	monthly
####	Space renovation/construction and Manufacturing	Permits	4.a Report on the submission of permits for space renovation/construction, as appropriate	Necessary permits are submitted to the appropriate administrative bodies for space renovation/construction	8/10/2020
####	Space renovation/construction and Manufacturing	Inspections	4.b Documentation of completed and passed inspections for renovated/constructed space, as	Necessary inspections are completed successfully for renovated/constructed space	according to timeline in deliverable 2.a
####	Space renovation/construction and Manufacturing	Renovation/construction plans	4.c Final engineering drawings and environmental control specifications completed for renovated/constructed space	Renovation/construction plans complete that define space/layout and environmental control specifications	according to timeline in deliverable 2.a

14	Space renovation/construction and Manufacturing	Quotes and orders for equipment	4.d Quotes from vendors and documentation of orders for equipment for additional/modified production lines	Orders placed with selected vendors for equipment/components necessary for new/modified production lines	according to timeline in deliverable 2.a
15	Space renovation/construction and Manufacturing	Space renovation/construction and installation of equipment	4.e Report of completed space renovation and/or construction, and installation of equipment for increasing production capacity	Complete space renovation/construction and installation of equipment	according to timeline in deliverable 2.a
16	Space Renovation/construction and Manufacturing	Debug, validate, and perform safety studies	4f. Report on the debugging, validation and safety studies of new equipment/assembly/production lines	New equipment and assembly/production lines are debugged/studied/validated to the level of performance of existing Sofia SARS Antigen FIA test manufacturing	according to timeline in deliverable 2.a
17	Scaled Manufacturing Production	Scale-up manufacturing	5.a Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	Production of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	8/31/2020
18	Scaled Manufacturing Production	Scale-up manufacturing	5.b Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	Production of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	12/31/2020
19	Scaled Manufacturing Production	Scale-up manufacturing	5.c Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	Production of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	3/31/2021
20	Scaled Manufacturing Production	Scale-up manufacturing	5.d Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	Production of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	5/15/2021
21	Scaled Manufacturing Production	Scale-up manufacturing	5.e Report on the demonstration of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	Production of increased capacity to (b)(4) Sofia SARS Antigen FIA tests/day	6/30/2021
22	Scaled Manufacturing Production	Scale-up manufacturing	5.f Report on the demonstration of increased capacity to (b)(4) Sofia Analyzers per month	Production of increased capacity to (b)(4) Sofia Analyzers/month	12/31/2020
23	Standardized electronic data transmission	Capability or plan for standardized electronic data transmission	6. Report on the demonstrated capability for using FHIR-based APIs for standardized electronic data transmission, or a plan for implementing such a capability over a period not to exceed 12 months	Capability or plan for using FHIR-based APIs for the standardized electronic data transmission of results to patients, providers and public health authorities and receipt of order from provider, with ability to integrate digital software from test prescription to transmission of results. Where applicable, such FHIR-based APIs should meet implementation specifications outlined by the Office of the National Coordinator for Health Information Technology in the 21st Century Cures Act final rule (published in the Federal Register on 6/1/2020), meet HHS requirements on laboratory data reporting released on 6/4/2020, disclose the unique device identifier(s) associated with the diagnostic, and use LOINC for communicating laboratory observations. Consult https://www.healthit.gov/curesrule/ for most recent updates	8/31/2020
24	Sustainability plan	Sustained supply chain and production capacity plan	7. Sustained supply chain and production capacity plan for the Sofia SARS Antigen FIA test and Sofia Analyzer	The plan clearly describes how the supply chain and production capacity will be sustained to meet the demands of SARS-CoV-2 testing	12/31/2021

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER: 5766209

PAGE 1 OF 21

2. CONTRACT NO.: 75N92020C00014

3. AWARD/EFFECTIVE DATE: 07/30/2020

4. ORDER NUMBER:

5. SOLICITATION NUMBER:

6. SOLICITATION ISSUE DATE:

7. FOR SOLICITATION INFORMATION CALL: a. NAME: NATALIE BRUNING

b. TELEPHONE NUMBER (No collect calls): +1 301 827 7528

8. OFFER DUE DATE/LOCAL TIME:

9. ISSUED BY CODE: NHLBI

Natalie Bruning
NIH/NHLBI
6701 Rockledge Dr
RKL II, Rm 6110
Bethesda, MD 20892-7511

10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:

☐ SMALL BUSINESS
☐ HUBZONE SMALL BUSINESS
☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
☐ EDWOSB
☐ 8(A)

NAICS: 334516

SIZE STANDARD: 1,000

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED ☒ SEE SCHEDULE

12. DISCOUNT TERMS:

☐ 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

13b. RATING:

14. METHOD OF SOLICITATION ☐ RFQ ☐ IFB ☐ RFP

15. DELIVER TO CODE: TDP, BTHOFF

Two Democracy Plaza, Bethesda Off C
2 Democracy Plaza
6707 Democracy Blvd
Bethesda MD 20817

16. ADMINISTERED BY CODE: NIBIB

Michael Wolfson
NIH/NIBIB
6707 Democracy Blvd
DEM II, Rm 200
Bethesda, MD 20892-7511

17a. CONTRACTOR/OFFEROR CODE: FACILITY CODE:

MESA TECH INTERNATIONAL INC:1186920
Attn: Ingo Chakravarty
6190 CORNERSTONE CT E
SUITE 220
SAN DIEGO CA 92121-4701

TELEPHONE NO. 858-692-9870

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY CODE: NHLBI INV-BR-A

Approved By, NHLBI Branch A Invoice
Paid By: NIH Commercial Accounts Br
2115 East Jefferson St, MSC 8500
Room 4B-432
Bethesda, MD 20892-8500

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Easy To Use, Low-Cost Molecular-Based SARS-CoV-2 Test, Highly Scalable Rapid Acceleration of Diagnostics (RADx) Program: Tech Project #2244 Mesa Biotech, Inc. Period of Performance: 07/30/2020 to 07/29/2021				
1	RADx Tech Project #2244 - Mesa - Critical design Continued ...				(b)(4)

(Use Reverse and/or Attach Additional Sheets as Necessary)

25. ACCOUNTING AND APPROPRIATION DATA: See schedule

26. TOTAL AWARD AMOUNT (*For Govt. Use Only*): $4,991,604.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☒ ARE ☐ ARE NOT ATTACHED.

☐ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN ______ COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: ______ OFFER DATED ______. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR: (b)(6)

31a. UNITED STATES OF AMERICA (*SIGNATURE OF CONTRACTING OFFICER*): Allison M. Cristman -S Digitally signed by Allison M. Cristman -S Date: 2020.07.30 12:51:51 -04'00'

30b. NAME AND TITLE OF SIGNER (*Type or print*): Ingo Chakravarty, President & CEO

30c. DATE SIGNED: July 30, 2020

31b. NAME OF CONTRACTING OFFICER (*Type or print*): ALLISON M. CRISTMAN

31c. DATE SIGNED: 07/30/2020

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)
Prescribed by GSA - FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	review and risk analysis Obligated Amount: (b)(4) Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 08/03/2020 Project Data: 151201.2020.300.COVID-19.DIAG.HN81 NIBIB OD OFFICE OF THE DIRECTOR.25235 ALL OTHER NON-FED SERVCS.07/29/2020 Accounting Info: 08039820200DAD.2020.83.8100.EM81000000C.E.C4400.406.COVD.25235.61000001.9999.9999.9999 Funded: (b)(4)				
2	RADx Tech Project #2244 - Mesa - Semi-automated implementation plan Obligated Amount: (b)(4) Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 08/17/2020 Project Data: Continued ...				(b)(4)

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: ____________

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32c. DATE

32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER

☐ PARTIAL ☐ FINAL

34. VOUCHER NUMBER

35. AMOUNT VERIFIED CORRECT FOR

36. PAYMENT

☐ COMPLETE ☐ PARTIAL ☐ FINAL

37. CHECK NUMBER

38. S/R ACCOUNT NUMBER

39. S/R VOUCHER NUMBER

40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT

41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

41c. DATE

42a. RECEIVED BY *(Print)*

42b. RECEIVED AT *(Location)*

42c. DATE REC'D *(YY/MM/DD)*

42d. TOTAL CONTAINERS

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75N92020C00014	PAGE 3	OF 21

NAME OF OFFEROR OR CONTRACTOR
MESA TECH INTERNATIONAL INC:1186920

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	151201.2020.300.COVID-19.DIAG.HN81 NIBIB OD OFFICE OF THE DIRECTOR.25235 ALL OTHER NON-FED SERVCS.07/29/2020 Accounting Info: 08039820200DAD.2020.83.8100.EM81000000C.E.C4400.406.COVD.25235.61000001.9999.9999.9999 Funded: (b)(4)				
3	RADx Tech Project #2244 - Mesa - Phase 1 of Semi-automated production plan Obligated Amount: (b)(4) Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 08/31/2020 Project Data: 151201.2020.300.COVID-19.DIAG.HN81 NIBIB OD OFFICE OF THE DIRECTOR.25235 ALL OTHER NON-FED SERVCS.07/29/2020 Accounting Info: 08039820200DAD.2020.83.8100.EM81000000C.E.C4400.406.COVD.25235.61000001.9999.9999.9999 Funded: (b)(4)				(b)(4)

PART I – THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This Letter Contract forms a preliminary understanding between Mesa Biotech, Inc. (Mesa) and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Tech (RADx-Tech) to increase the testing capacity of high throughput labs by scaling up late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. Issuance of this Letter Contract authorizes the Contractor to immediately begin the activities necessary to perform the requirements as identified in the Statement of Objectives covering the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public.

Mesa has developed an Easy to Use, Low-Cost Molecular-Based SARS-CoV-2 Test, Highly Scalable. The Accula SARS-CoV-2 test kit is a single-use molecular diagnostic test utilizing PCR and lateral flow technologies for the qualitative, visual detection of coronavirus SARS-CoV-2 viral RNA. The scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

This Letter Contract has been issued based on the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the Point of Care Technology Research Network (POCTRN) application review process. The Contractor's inability to meet the requirements as defined within this Letter Contract and proposed within the POCTRN application process may result in the termination of the Letter Contract in accordance with the termination clauses contained herein.

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for the Letter Contract is $5,991,604.

Payment Schedule

Milestone	**Amount**
Complete critical design review (CDR) and risk analysis to finalize design of semi-automated line	(b)(4)
Finalize semi-automated implementation plan; maintain production capacity of (b)(4) (b)(4)	
Complete first phase of semi-automated production plan; maintain production capacity of (b)(4)	

b. The parties agree to negotiate Options for additional work during the definitization of the contact.

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. The parties acknowledge and agree that the situation around COVID-19 is highly dynamic, evolving rapidly, and subject to significant uncertainty. The Letter Contract is being executed on an expedited timeline to meet an urgent and compelling government need without the benefit of prior negotiation. Thus, the parties will negotiate in good faith to ensure that the definitized contract reflects an appropriate allocation of risk and responsibility and that it is consistent with the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance. Until the Performance Work Statement (PWS) is finalized the Statement of Objective (SOO) will govern.

b. Funding in the amount not to exceed $5,991,604 is made available under this letter contract. The contractor shall not incur costs in excess of this amount.

c. The parties anticipate that the definitive contract resulting from this Letter Contract will include a negotiated firm fixed price not to exceed (b)(4) and an option value not to exceed (b)(4) for a total price including all options not to exceed $18,536,704.

d. Commercial Item Status: The services provided by the Contractor under the Letter Contract and any definitized contract constitute commercial item services, and the terms of any definitized contract will reflect that understanding.

e. Performance Work Statement: The parties will negotiate the Performance Work Statement in the process of contract definitization to fairly reflect the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between application submission through letter contract issuance.

f. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

g. The parties agree prior to negotiate further the terms of milestone payments to include in the definitized contract. In the negotiation, the parties will consider terms addressing liquidation of milestone payments.

h. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA); the Contractor shall copy us on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EUA services provided under this Letter Contract constitute a commercial service to detect SARS-CoV-2.

i. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States.

j. In accordance with the goals of the RADx program, the tests produced under this contract are to be sold within the U.S. and its territories; provided, however, that, to the extent there is insufficient demand within the U.S. and its territories for the tests produced up to the additional manufacturing capacity funded by NIH and then available (as described in the Schedule of Deliverables), contractor will be permitted to sell such tests outside the U.S. and its territories. The factors, process and mechanism to determine whether contractor has insufficient demand for the tests up to the then-available capacity will be determined in the definitive contract.

k. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of this Letter Contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

l. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to perform the deliverables and achieve the milestones in accordance with the Statement of Objectives and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment shall be arranged by contractor at no additional cost to the Government.

m. Letter Contract Termination: In accordance with 52.212-4(l), the Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

n. Letter Contract Termination: In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

o. **Security and Privacy of Protected Health Information (PHI) processed under this contract**: In the event that the Contractor meets the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the contractor shall comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO)and the Contracting Officer's Representative (COR).

p. Any imported materials must be FDA-approved for use in the U.S.

q. The parties agree to address HHS Information Security and Privacy Requirements, as applicable, during definitization of the contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 27, 2020, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Leter Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Reporting requirements TBD.
Placeholder: De-identified data for NIH research database

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and the milestones to be achieved.

b. Inspection and acceptance will be performed utilizing the success criteria outlined in the deliverable schedule.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Letter Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule.

The deliverables or documentation thereof shall be submitted to the Contracting Officer or designated Contracting Officer Representative (COR).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Lynn Furtaw
Telephone: 301-827-7713
Email: lynn.furtaw@nih.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to:

1) direct or negotiate any changes in the Satement of Objectives or Performance Work Statement;
2) modify or extend the period of performance;
3) change the deliverables or milestones schedule;
4) authorize reimbursement to the Contractor for any costs incurred during the performance of this Letter Contract;
5) otherwise change any terms and conditions of this Letter Contract; or
6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of this Letter Contract.

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing this Letter Contract and the COR supporting the CO.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Olga Hartman, PhD
Telephone: 443-350-7696
Email: olga.hartman.civ@mail.mil

The COR is responsible for:

(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
(2) interpreting the Statement of Objectives and any other technical performance requirements;
(3) performing technical evaluation as required;
(4) performing technical inspections and acceptances required by this Letter Contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this contract is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or contracts (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the contract to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100%.

(b)(6)
Primary Program Manager

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

a. The Contract Title is: RADx Tech Mesa 2244 – Easy to Use, Low-Cost Molecular-Based SARS-CoV-2 Test, Highly Scalable
b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.
c. Invoice Instructions are attached and made part of this Letter Contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

   1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in this Letter Contract or requested by the Contracting Officer.

    a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

        NHLBI Branch B Central Mailbox (NHLBIContractsBranchB@mail.nih.gov)

        NIH centralized invoice email box: invoicing@nih.gov

2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this task order is **NHLBI**.

    b. Central Point of Distribution. For the purpose of this Task Order, the Central Point of Distribution is **NHLBI Branch B Invoices**.

    c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

    e. Invoice Matching Option. This Letter Contract requires a **two-way** match.

    f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

    g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see Section B – PRICES/OPTION).

d. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITONAL CONTRACT CLAUSES

ARTICLE H.1. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this Letter Contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the Letter Contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this Letter Contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.2. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this Letter Contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92020C00014.

ARTICLE H.3. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office of Inspector
General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FAR Clause 52.212-3, Offeror Representations and Certifications-Commercial Items
b. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
c. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
d. FAR Clause 52.204-2, Security Requirements (August 1996).
    1. Alternate I (April 1984) is not applicable to this contract.
    2. Alternate II (April 1984) is not applicable to this contract.
e. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
f. FAR Clause 52.204-13, System for Award Management Maintenance
g. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
h. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
i. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
j. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
k. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
l. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).
m. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
n. FAR Clause 52.224-2, Privacy Act (April 1984).
o. FAR Clause 52.227-11 Patent Rights-Ownership by the Contractor
p. FAR Clause 52.227-14, Rights in Data - General (May 2014).
q. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).
r. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors

ARTICLE I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of this Letter Contract and returning to the Contracting Officer not later than July 29, 2020 at 10:00 p.m. Eastern. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this Letter Contract, the Contractor is not authorized to make expenditures or incur obligations exceeding **$5,991,604** dollars.

(b) The maximum amount for which the Government shall be liable if this Letter Contract is terminated is **$5,991,604** dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Firm Fixed Price (FFP) definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Firm Fixed Price proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

The schedule for definitizing this contract is as follows:

Definitization Schedule	Date
Letter Contract Post Award Kick Off meeting	07/31/2020
Contractor Technical and Revised Price Proposal Submittal including other than certified cost or pricing data	08/14/2020
Project Officer's Technical Questionnaire/Technical Evaluation &Review	08/20/2020
Negotiations Start	08/21/2020
Definitization of Letter Contract	09/10/2020

(b) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of this Letter Contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, this Letter Contract shall be governed by-
   (i) All clauses required by the FAR on the date of execution of this Letter Contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);
   (ii) All clauses required by law as of the date of the Contracting Officer's determination; and
   (iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this Letter Contract shall continue in effect, except those that by their nature apply only to a Letter Contract.

4. FAR Clause 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) Definitions. As used in this clause–

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public websites) or simple transactional information, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

5. **FAR 52.212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (Jul 2020)**

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: [*Contracting Officer check as appropriate*.]

Selections will be made by the Contracting Officer during definitization.

__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUNE 2020), with *Alternate I* (OCT 1995) (41U.S.C.4704 and 10 U.S.C. 2402).
__ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509)).
__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
__ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).
__ (5) [Reserved].
__ (6) 52.204-14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).
__ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).
__ (10) [Reserved].

__ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).

  __ (ii) Alternate I (MAR 2020) of 52.219-3.

__ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).

  __ (ii) Alternate I (Mar 2020) of 52.219-4.

__ (13) [Reserved]

__ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).

  __ (ii) Alternate I (MAR 2020) of 52.219-6 .

__ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).

  __ (ii) Alternate I (MAR 2020) of 52.219-7.

__ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).

__ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).

  __ (ii) Alternate I (Nov 2016) of 52.219-9.

  __ (iii) Alternate II (Nov 2016) of 52.219-9.

  __ (iv)Alternate III (Jun 2020) of 52.219-9.

  __ (v)AlteRNATE IV (JUN 2020) OF 52.219-9

__ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).

  __ (ii) Alternate I (MAR 2020) of 52.219-13.

__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).

__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).

__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar 2020) (15 U.S.C. 657f).

__ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).

__ (ii) Alternate I (MAR 2020) of 52.219-28.

__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).

__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).

__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C. 644(r)).

__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).

__ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

__ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)

__ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

__ (30) (i) 52.222-26, Equal Opportunity (SEP 2016) (E.O.11246).

  __ (ii) Alternate I (FEB 1999) of 52.222-26.

__ (31) (i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

  __ (ii) Alternate I (JUL 2014) of 52.222-35.

__ (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

  __ (ii) Alternate I (JUL 2014) of 52.222-36.

__ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

__ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

__ (35) (i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

  __ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

__ (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

__ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

  __ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).

__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).

__ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (OCT 2015) of 52.223-13.

__ (41) (i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (Jun2014) of 52.223-14.

__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).

__ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (JUN 2014) of 52.223-16.

__ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).

__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).

__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).

__ (47) (i) 52.224-3 Privacy Training (JAN 2017) (5 U.S.C. 552 a).

  __ (ii) Alternate I (JAN 2017) of 52.224-3.

__ (48) 52.225-1, Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).

__ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

  __ (ii) Alternate I (May 2014) of 52.225-3.

  __ (iii) Alternate II (May 2014) of 52.225-3.

  __ (iv) Alternate III (MAY 2014) of 52.225-3.

__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

__ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal

Year 2008; 10 U.S.C. 2302Note).

__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).

__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).

__ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).

__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).

__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).

__ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

  __ (ii) Alternate I (Apr 2003) of 52.247-64.

  __ (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[*Contracting Officer check as appropriate.*]

__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).

__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).

__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).

__ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).

__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the

Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).

(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(v) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(vi) 52.222-21, Prohibition of Segregated Facilities (APR 2015).

(vii) 52.222-26, Equal Opportunity (SEP 2015) (E.O.11246).

(viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

(x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).

(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.

(xii) 52.222-41, Service Contract Labor Standards (Aug2018) (41 U.S.C. chapter 67).

(xiii) (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O 13627).

(B) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).

(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY2014) (41 U.S.C. chapter 67).

(xvi) 52.222-54, Employment Eligibility Verification (OCT 2015) (E.O. 12989).

(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).

(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).

(xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).

(B) Alternate I (Jan 2017) of 52.224-3.

(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.

(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

6. FAR 52.217-7 Option for Increased Quantity – Separately Priced Line Item

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within the period of performance of the contract. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J LIST OF ATTACHMENTS

1. Statement of Objectives
    a. Appendix 1: Schedule of Deliverables/Milestones

Statement of Objectives

Program Title: Rapid Acceleration of Diagnostics (RADx) – Tech
Project Title: Easy to Use, Low-Cost Molecular-Based SARS-CoV-2 Test, Highly Scalable (Mesa Biotech, Inc.)
Agency: National Institute of Biomedical Imaging and Bioengineering (NIBIB) / National Institutes of Health (NIH)

1. Background

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has an open solicitation for proposals to provide up to $500 million across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. Rapid Acceleration of Diagnostics (RADx), is a fast-track technology development program that leverages the National Institutes of Health (NIH) Point-of-Care Technology Research Network (POCTRN). RADx will support novel solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. RADx is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

2. Purpose and Objectives

NIBIB is providing substantial support to accelerate the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2, the virus that causes COVID-19. NIBIB will support the full range of product development including commercialization and product distribution. The ultimate goal of the RADx program – across multiple projects/contracts – is to make millions of tests per week available to the American public, particularly those most vulnerable to and/or disproportionately impacted by COVID-19, in the late summer of 2020, and having even more tests available in time for the 2020–2021 flu season.

To meet the accelerated timelines, RADx has assembled a national network of expert technical, clinical, manufacturing, and regulatory advisors who will provide individualized assistance for project development and commercialization. Funding for projects selected for this program will be dependent on successfully meeting aggressive project milestones. NIBIB will provide financial and in-kind support to accelerate the entire product life-cycle, from design to market, for projects that meet milestones successfully. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, the Department of Defense, as well as commercial and private entities to propel technologies developed by RADx into widespread use.

The RADx program will consider innovations at all stages of readiness to circumvent current limitations to SARS-CoV-2 testing capacity, including:

- Early stage: transformative innovations based on novel testing strategies that have potential for major scale up
- Mid stage: technologies using novel testing strategies that have demonstrated capability but need further validation, regulatory approval, and scale up
- Advanced stage (RADx ATP): modification and optimization of existing SARS-CoV-2 testing approaches, including clinical laboratory tests, that can dramatically increase testing capacity. Note: This arm of the RADx program is addressed under a separate Acquisition Plan.

Design features might include technical innovations that:

- Improve analytical performance, e.g., sensitivity, specificity, dynamic range, limit of detection, reliability, accuracy, speed (time to test result) and throughput
- Enhance operational performance through, e.g., development of a patient- and user-friendly design, use of alternative sampling strategies (e.g., saliva, exhaled breath), integration with mobile-devices, designs for home-based use or strategies to overcome bottlenecks with current testing approaches
- Improve access and reduce the cost of testing.

3. Scope

RADx-Tech is a two phase program. All applications undergo an intensive week-long risk assessment by a panel of expert technical, clinical, manufacturing, and regulatory advisors. If the proposed technology meets viability metrics, projects may be selected to enter phase one.

Phase one, performed under a separate funding mechanism, consists of an accelerated research and development program in which the awardee receives both financial support and in-kind services through RADx grant funding. This outcome of this work is a fully instantiated technology ready for clinical validation, regulatory authorization, production and commercialization.

Phase two, or Work Package 2, of the program, executed under this contract, includes completing clinical validation and implementation of production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

4. Performance Objectives (Required Results)

A. Contract recipients have completed major research and development efforts and are focused in phase two on completion of required clinical validation, preparation of regulatory submissions, scale-up of production capabilities, and preparation for full commercialization of their product – a testing technology. Every contract will encompass similar expectations and milestones concerned with:
   1. meeting regulatory requirements, resulting in regulatory authorization for sale and use of the test;
   2. instantiation of agreed-upon production capacity;
   3. meeting agreed-upon production goals; and
   4. implementation of an agreed-upon commercial strategy to bring the test to market in a timeframe that will impact the COVID-19 pandemic as soon as possible.

B. Contract funding in phase two is structured in order to reduce risk to the Government, and is dependent on achievement of specific milestones in the Schedule of Deliverables, according to the Payment Schedule.

C. The contractor must use a SARS-Cov-2 test with FDA EUA, indicating a combination of sensitivity, specificity, and usability appropriate to the intended use according to FDA and/or CDC guidance, as applicable.

D. The contractor must make the product available for independent regulatory/validation assessment. The independent assessor will be selected by the Government.

5. Contract Type

The contract type is Firm Fixed Price.

6. Place of Performance

The place of performance will be at the contractor's site.

7. Period of Performance

The period of performance is July 30, 2020 through July 29, 2021.

8. Option for Increased Services

Options for increased quantity/services will be contemplated for each contract awarded under RADx Tech. Options include purchase of approximately 300 docks and 15,000 cassettes per month for four months to support an Operation Warp Speed vaccine trial.

9. Reporting Requirements/Deliverables

The following reporting requirements will required:

Item No.	Reporting Requirements	Due Date
1	Bi-weekly Production Status Report – to include current plant production capacity and output on a per-week basis, and a description of any issues/problems encountered with plans for solution/mitigation (e.g., delays in meeting deliverables, supply chain issues, design/validation issues, etc.)	Bi-weekly until the end of February 2021
2	Monthly Production Report - Current plant production capacity and break down capacity and output on a per-line/per week basis	Monthly

See Appendix 1 for List of Deliverables/Milestones

10. Other Requirements

A. The contractor must meet regularly (at least weekly) with NIH officials to update on progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion. When guided by NIH officials, the contractor must be willing to collaborate and cooperate with external organizations as needed to meet the contract goals in a manner which will not infringe contractor commercial or intellectual property rights.

11. Appendices

1. List of Deliverables/Milestones

Appendix 1: List of Deliverables/Milestones

No	Objective Defined	Milestone Defined	Deliverable	Success Criteria/Objective Evidence	Deliverable Due Date	Fixed Price
1	(b)(4)					(b)(4)
2						
3						
4						
5						
6						
7						
8						
9a						
9b						
10						
11						
12						
13						
					Total	

OPTIONAL WORK: (to be negotiated)

Description	Unit Price	Quantity	Estimated Not-To-Exceed Total
(b)(4)	(b)(4)		

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEMS

OFFEROR TO COMPLETE BLOCKS 12, 17, 23, 24, & 30

1. REQUISITION NUMBER: 5763920

PAGE 1 OF 20

2. CONTRACT NO.: 75N92020C00009

3. AWARD/ EFFECTIVE DATE:

4. ORDER NUMBER:

5. SOLICITATION NUMBER:

6. SOLICITATION ISSUE DATE:

7. **FOR SOLICITATION INFORMATION CALL:** a. NAME: LINDA SMITH b. TELEPHONE NUMBER *(No collect calls)*: +1 301 827-7741

8. OFFER DUE DATE/LOCAL TIME:

9. ISSUED BY CODE NHLBI

National Institutes of Health
National Heart, Lung, and Blood Institute
Bethesda, MD 20892-7511

10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR:

☐ SMALL BUSINESS
☐ HUBZONE SMALL BUSINESS
☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS
☐ WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOMEN-OWNED SMALL BUSINESS PROGRAM
☐ EDWOSB
☐ 8(A)

NAICS: 334516

SIZE STANDARD: 1,000

11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED ☒ SEE SCHEDULE

12. DISCOUNT TERMS

☐ 13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

13b. RATING

14. METHOD OF SOLICITATION ☐ RFQ ☐ IFB ☐ RFP

15. DELIVER TO CODE TDP, BTHOFF

Two Democracy Plaza, Bethesda Off C
2 Democracy Plaza
6707 Democracy Blvd
Bethesda MD 20817

16. ADMINISTERED BY CODE NIBIB

National Institutes of Health
National Institute of Biomedical Imaging and Bioengineering
Bethesda, MD 20892-7511

17a. CONTRACTOR/ OFFEROR CODE FACILITY CODE

FLUIDIGM CORPORATION:1157584
2 TOWER PLACE SUITE 2000
SOUTH SAN FRANCISCO CA 940801826

TELEPHONE NO. –

☐ 17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER

18a. PAYMENT WILL BE MADE BY CODE NHLBI INV-BR-A

Approved By, NHLBI Branch A Invoice
Paid By: NIH Commercial Accounts Br
2115 East Jefferson St, MSC 8500
Room 4B-432
Bethesda, MD 20892-8500

18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	NIBID: 75N92020C00009 Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm - Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva Period of Performance: 07/30/2020 to 07/29/2021				
1	Stage 1 - Test Verification Obligated Amount: (b)(4) Delivery To: Bldg.31/RM 1C31 Continued ...				(b)(4)

(Use Reverse and/or Attach Additional Sheets as Necessary)

25. ACCOUNTING AND APPROPRIATION DATA

26. TOTAL AWARD AMOUNT *(For Govt. Use Only)*: $12,151,000.00

☐ 27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4. FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.

☒ 27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4. FAR 52.212-5 IS ATTACHED. ADDENDA ☒ ARE ☐ ARE NOT ATTACHED.

☒ 28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 1 COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED.

☐ 29. AWARD OF CONTRACT: OFFER DATED . YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:

30a. SIGNATURE OF OFFEROR/CONTRACTOR: (b)(6)

30b. NAME AND TITLE OF SIGNER *(Type or print)*: S. Christopher Linthwaite, President and CEO

30c. DATE SIGNED: 7/29/2020

31a. UNITED STATES OF AMERICA *(SIGNATURE OF CONTRACTING OFFICER)*: Roxane S. Burkett -S Digitally signed by Roxane S. Burkett -S Date: 2020.07.30 07:36:45 -04'00'

31b. NAME OF CONTRACTING OFFICER *(Type or print)*: ROXANE S. BURKETT

31c. DATE SIGNED:

AUTHORIZED FOR LOCAL REPRODUCTION
PREVIOUS EDITION IS NOT USABLE

STANDARD FORM 1449 (REV. 2/2012)
Prescribed by GSA - FAR (48 CFR) 53.212

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
	Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 08/08/2020				
2	Stage 1A - Design Review Obligated Amount: (b)(4) Delivery To: Bldg.31/RM 1C31 Product/Service Code: Q301 Product/Service Description: MEDICAL- LABORATORY TESTING Delivery: 09/12/2020				(b)(4)

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED ☐ INSPECTED ☐ ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS NOTED: ____________

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32c. DATE

32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER

☐ PARTIAL ☐ FINAL

34. VOUCHER NUMBER

35. AMOUNT VERIFIED CORRECT FOR

36. PAYMENT

☐ COMPLETE ☐ PARTIAL ☐ FINAL

37. CHECK NUMBER

38. S/R ACCOUNT NUMBER

39. S/R VOUCHER NUMBER

40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT

41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

41c. DATE

42a. RECEIVED BY *(Print)*

42b. RECEIVED AT *(Location)*

42c. DATE REC'D *(YY/MM/DD)*

42d. TOTAL CONTAINERS

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SERVICES

This Letter Contract forms a preliminary understanding between Fluidigm Corporation and the National Institutes of Health (NIH) and is issued as a result of the Rapid Acceleration of Diagnostics Advanced Technology Platforms (RADx-ATP) to increase the testing capacity of high throughput labs by scaling up late stage testing platforms for detecting SARS-CoV-2, the virus that causes COVID-19. Issuance of this Letter Contract authorizes the Contractor to immediately begin the activities necessary to perform the requirements as identified in the Statement of Objectives covering the full range of activities needed to increase capacity and optimize throughput necessary to distribute a viable product to the public.

The scope of work executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public. Fluidigm technology to support this effort will be to scale up the Integrated Fluidic Circuit (IFC) and completion of the multiplex assay development system for rapid acceleration of testing.

This Letter Contract has been issued based on the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the Point of Care Teachnology Research Network (POCTRN) application review process. The Contractor's inability to meet the requirements as defined within this Letter Contract and proposed within the POCTRN application process may result in the termination of the Letter Contract in accordance with the termination clauses contained herein.

ARTICLE B.2. PRICES

a. The total Firm Fixed Price (FFP) amount for this Letter Contract is $12,151,000.

Payment Schedule *[See complete breakdown in Deliverable Schedule]*	
Milestone	**Amount**
Stage 1 – Test Verification	(b)(4)
Stage 1A – Design Review	[redacted]
Total	**$12,151,000**

ARTICLE B.3. ADVANCE UNDERSTANDINGS

a. The parties acknowledge and agree that the situation around COVID-19 is highly dynamic, evolving rapidly, and subject to significant uncertainty. The Letter Contract is being executed on an expedited timeline to meet an urgent and compelling government need without the benefit of prior negotiation. Thus, the parties will negotiate in good faith to ensure that the definitized contract reflects an appropriate allocation of risk and responsibility and that it is consistent with the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance. Until the Performance Work Statement (PWS) is finalized the Statement of Objective (SOO) will govern.

b. The parties anticipate that the definitive contract resulting from this Letter Contract will include a negotiated firm fixed price not to exceed $36,834,000. The amount of funding provided for this Letter Contract is stated in Article B.2 avove, the contractor shall not incur costs in excess of this amount.

c. Commercial Item Status: The services provided by the Contractor under the Letter Contract and any definitized contract constitute commercial item services, and the terms of any definitized contract will reflect that understanding.

d. Performance Work Statement: The parties will negotiate the Performance Work Statement in the process of contract definitization to fairly reflect the application and preliminary work file submitted by the contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between application submission through letter contract issuance.

e. HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System.

f. The parties agree prior to negotiate further the terms of milestone payments to include in the definitized contract. In the negotiation, the parties will consider terms addressing liquidation, time and criteria of milestone payments.

g. Successful performance under this contract requires the Contractor obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA); the Contractor shall copy us on all FDA correspondence related to the project, including email communications to and from the FDA. The FDA EUA services provided under this Letter Contract constitute a commercial service to detect SARS-CoV-2.

h. Fair Pricing: The Rapid Acceleration of Diagnostics (RADx) application review process determined the cost per test is competitive with the current market price. The Contractor must comply with applicable federal law to ensure that prices to consumers are offered at fair market rate and at a rate consistent with the objective to increase and improve testing in the United States and its territories.

i. In accordance with the goals of the RADx program, the tests manufactured under this contract are to be sold within the U.S. and its territories; provided, however, that, to the extent there is insufficient demand within the U.S. and its territories for the tests produced up to the additional manufacturing capacity funded by NIH and then available (as described in the Schedule of Deliverables), contractor will be permitted to sell such tests outside the U.S. and its territories. The factors, process and mechanism to determine whether contractor has insufficient demand for the tests up to the then-available capacity will be determined in the definitive contract.

j. Sharing Data and Reports: The Contractor will be required to provide data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of this Letter Contract. NIH may use the data to coordinate with other U.S. Government Agencies to accelerate development and deployment of innovative COVID-19 diagnostic tests, and ensure effective stewardship of federal funds. Sharing data within the federal government enables NIH to discuss the project's challenges and progress with federal agencies offering scientific, manufacturing, and logistics expertise. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, and the Department of Defense, and partnerships with State agencies to propel technologies developed by RADx into widespread use.

k. Contractor Facilities: The contractor shall certify that they will maintain their Facility and Equipment in satisfactory operating condition, as required to enable the contractor to perform the deliverables and achieve the milestones in accordance with the Statement of Objectives and all other applicable laws, regulations, rules or orders. Routine repairs, preventive maintenance, and service contracts for the Facility and Equipment shall be arranged by contractor at no additional cost to the Government.

l. FAR 52.212-4 (l), the Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges the Contractor can demonstrate to the satisfaction of the Government using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

m. Letter Contract Termination: In accordance with FAR 52.212-4(m), the Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

n. Security and Privacy of Protected Health Information (PHI) processed under this contract: The Contractor , shall meet the definition of either a Covered Entity or Business Associate under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The contractor shall therefore comply with the HIPAA regulatory standards set forth in the Code of Federal Regulations (CFR) 45 C.F.R. Part 160, Part 162, and Part 164. To the extent that the Contractor engages subcontractors or other Business Associates to provide services under this Contract, and such Subcontractors or Business Associates will receive or create protected health information (PHI) on behalf of the contractor, the contractor shall obtain satisfactory assurances from its business associate that the business associate will appropriately safeguard the protected health information. The satisfactory assurances must be in writing, whether in the form of a contract or other agreement between the Contractor and the business associate. In the event of a suspected or known security or privacy breach, in addition to following the procedures set forth in 45 C.F.R. Part 164, the contractor shall also immediately notify the NIH via the Contracting Officer (CO)and the Contracting Officer's Representative (COR).

o. The parties agree to address HHS Information Security and Privacy Requirements, as applicable, during definitization of the contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives, dated July 27, 2020, set forth in SECTION J – List of Attachments, attached hereto and made a part of this Leter Contract. Work to be performed shall be consistent with the application and preliminary work file submitted by the Contractor and subsequent documentation submitted during the application review process and the discussions between the parties that have taken place between date of application submission through Letter Contract issuance.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format only. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

> *Reporting requirements TBD.*
> *Placeholder: De-identified data for NIH research database*

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional instructions or specifications applicable to this contract other than the delivery instructions contained herein.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of deliverables to be performed and the milestones to be achieved.
b. Inspection and acceptance will be performed as identified in the contract requirements.

SECTION F - DELIVERIES OR PERFORMANCE ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

ARTICLE F.2. DELIVERIES

Satisfactory performance shall be deemed to occur upon performance of the work described in the Statement of Objectives Article in SECTION C of this Letter Contract and upon notice and acceptance by the Contracting Officer, or the duly authorized representative, in accordance with the stated deliverables schedule.

The deliverables or documentation there of shall be submitted to the Contracting Officer or designated Contracting Officer Representative (COR).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Name: Roxane Burkett
Telephone: 301-827-7535
Email: burkettr@nih.nhlbi.gov

The Contracting Officer is the only person with authority to act as agent of the Government under this task order. Only the Contracting Officer has authority to:

1) direct or negotiate any changes in the statement of work;
2) modify or extend the period of performance;
3) change the delivery schedule;
4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract;
5) otherwise change any terms and conditions of this contract; or
6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract.

All correspondence (including invoices) that proposes or otherwise involves waivers, deviations, or modifications to requirement shall be provided to the CO issuing the task order and the COR supporting the CO.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) is anticipated to represent the Government for the purpose of this contract:

Olga Hartman, PhD
Telephone: 443-350-7696
Email: olga.hartman.civ@mail.mil

The COR is responsible for:

(1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
(2) interpreting the Statement of Objectives and any other technical performance requirements;
(3) performing technical evaluation as required;
(4) performing technical inspections and acceptances required by this Letter Contract; and
(5) assisting in the resolution of technical problems encountered during performance.

The Government may unilaterally change the COR designation.

ARTICLE G.3. PRIMARY PROGRAM MANAGER

The Primary Program Manager specified in this task order is considered to be essential to work performance. At least 30 days prior to any changes to the individual listed below to other programs or task orders (or as soon as reasonably possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the change request (including proposed substitutions for primary program manager) to permit evaluation by the Government of the impact on performance under this task order. The Contractor shall not replace any primary program manager without the written consent of the Contracting Officer. The Government may modify the task order to add or delete primary program manager at the request of the contractor or Government. In no case shall the individual's effort exceed 100% across all task orders.

(b)(6) Senior Vice President, Operations
(b)(6) Vice President, R&D & PMO, Genomics

ARTICLE G.4. INVOICE SUBMISSION

In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all task order payment requests:

a. The Contract Title is: "Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva"
b. The Contract Line Items are defined within the Section 20. Schedule of Supplies/Services of the Standard Form 1449.
c. Invoice Instructions are attached and made part of this task order. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.

    a. One copy of the invoice shall be submitted to the approving official at the following email addresses:

        NHLBI Branch B Central Mailbox (NHLBIContractsBranchB@mail.nih.gov)

        NIH centralized invoice email box: invoicing@nih.gov

2. E-Mail: The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests (invoices):

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this task order is **NHLBI**.

    b. Central Point of Distribution. For the purpose of this Task Order, the Central Point of Distribution is **NHLBI Branch B Invoices**.

    c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is* *assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

e. Invoice Matching Option. This Task Order requires a **two-way** match.

f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance (see SF 1449, Attachment #2).

d. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

SECTION H - ADDITONAL CONTRACT CLAUSES

ARTICLE H.1. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.2. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institutes Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under Contract No: 75N92020C00009."

ARTICLE H.3. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services Office of Inspector
General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489 Washington, D.C. 20026

PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES

Selections will be made by the Contracting Officer during definitization

ARTICLE I.1. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FAR Clause 52.212-3 Offeror Representations and Certifications – Commercial Items (Jun 2020)
a. FAR Clause 52.212-4 Contract Terms and Conditions – Commercial Items (Oct 2018)
b. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015)
c. FAR Clause 52.204-2, Security Requirements (August 1996).
d. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).
e. FAR Clause 52.204-13, System for Award Management Maintenance
f. FAR Clause 52.204-18 Commercial and Government Entity Code Maintenance (July 2016)
g. FAR Clause 52.204-23 Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities

h. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations(November 2015).
i. FAR Clause 52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation -General (May 2014).
j. FAR Clause 52.222-29, Notification of Visa Denial (April 2015).
k. FAR Clause 52.223-15, Energy Efficiency in Energy-Consuming Products (December 2007).
l. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
m. FAR Clause 52.224-2, Privacy Act (April 1984).
n. FAR Clause 52.227-1, Aughorization and Consent (Jun 2020).
o. FAR Clause 52.227-3 Patent Indemnity (Apr 1984).
p. FAR Claus 52.227-11 Patent Rights-Ownership by the Contractor (May 2014).
q. FAR Clause 52.227-14, Rights in Data - General (May 2014).
r. FAR Clause 52.227-14, Rights in Data - General (May 2014) Alternate II (Dec 2007).
s. FAR Clause 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)

ARTICLE I.3. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during definitization. This contract incorporates the following clauses in full text.

1. FAR 52.216-23 - EXECUTION AND COMMENCMENT OF WORK (APR 1984)

The Contractor shall indicate acceptance of this letter contract by signing One Copy of the contract and returning them to the Contracting Officer not later than July 29, 2020 at 4:00 p.m. Eastern. Upon acceptance by both parties, the Contractor shall proceed with performance of the work, including purchase of necessary materials.

2. FAR 52.216-24 - LIMITATION OF GOVERNMENT LIABILITY (APR 1984)

(a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding $12,151,000 dollars.

(b) The maximum amount for which the Government shall be liable if this contract is terminated is $12,151,000 dollars.

3. FAR 52.216-25 - CONTRACT DEFINITIZATION (OCT 2010)

(a) A Firm Fixed Price (FFP) definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the letter contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a Firm Fixed Price proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal.

(b) The schedule for definitizing this contract is as follows:
Estimated date for start of negotiations: 8/3/2020
Target date for definitization: 9/25/2020

Definitization Schedule	Date

Statement of Work Review	7/27/2020
Issuance of Letter Contract	7/30/2020
Letter Contract Post Award Kick Off meeting	7/31/2020
Contractor Price Proposal Submittal	8/5/2020
Business and Technical Review	8/12/2020
Negotiations Start	8/13/2020
Request Budget and Price Breakdown	9/7/2020
Definitization of Letter Contract	9/25/2020

(c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause.

(1) After the Contracting Officer's determination of price or fee, the contract shall be governed by-

(i) All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);

(ii) All clauses required by law as of the date of the Contracting Officer's determination; and

(iii) Any other clauses, terms, and conditions mutually agreed upon.

(2) To the extent consistent with paragraph (c)(1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract.

4. FAR Clause 52.204-21, Basic Safeguarding of Covered Contractor Information Systems **(Jun 2016)**

(a) Definitions. As used in this clause–

Covered contractor information system means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

Federal contract information means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public websites) or simple transactional information, such as necessary to process payments.

Information means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

Safeguarding means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

5. **FAR 52.214-5** Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items **(Jul 2020)**

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items. Selections will be made by the Contracting Officer during definitization:

__ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (JUNE 2020), with *Alternate I* (OCT 1995) (41U.S.C.4704 and 10 U.S.C. 2402).
__ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509)).
__ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (JUN 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.)
__ (4) 52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020) (Pub. L. 109-282) (31 U.S.C. 6101 note).
__ (5) [Reserved].
__ (6) 52.204-14, Service Contract Reporting Requirements (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (7) 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (OCT 2016) (Pub. L. 111-117, section 743 of Div. C).
__ (8) 52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (JUN 2020) (31 U.S.C. 6101 note).
__ (9) 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (OCT 2018) (41 U.S.C. 2313).
__ (10) [Reserved].
__ (11) (i) 52.219-3, Notice of HUBZone Set-Aside or Sole-Source Award (MAR 2020) (15 U.S.C. 657a).
    __ (ii) Alternate I (MAR 2020) of 52.219-3.
__ (12) (i) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Mar 2020) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
    __ (ii) Alternate I (Mar 2020) of 52.219-4.
__ (13) [Reserved]
__ (14) (i) 52.219-6, Notice of Total Small Business Set-Aside (Mar 2020) of 52.219-6 (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-6 .
__ (15) (i) 52.219-7, Notice of Partial Small Business Set-Aside (Mar 2020) (15 U.S.C. 644).
    __ (ii) Alternate I (MAR 2020) of 52.219-7.
__ (16) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
__ (17) (i) 52.219-9, Small Business Subcontracting Plan (Jun 2020) (15 U.S.C. 637(d)(4)).
    __ (ii) Alternate I (Nov 2016) of 52.219-9.
    __ (iii) Alternate II (Nov 2016) of 52.219-9.
    __ (iv)Alternate III (Jun 2020) of 52.219-9.
    __ (v)ALTERNATE IV (JUN 2020) OF 52.219-9
__ (18) (i) 52.219-13, Notice of Set-Aside of Orders (Mar 2020) (15 U.S.C. 644(r)).
    __ (ii) Alternate I (MAR 2020) of 52.219-13.
__ (19) 52.219-14, Limitations on Subcontracting (Mar 2020) (15 U.S.C. 637(a)(14)).
__ (20) 52.219-16, Liquidated Damages-Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
__ (21) 52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Mar

2020) (15 U.S.C. 657f).

__ (22) (i) 52.219-28, Post Award Small Business Program Rerepresentation (May 2020) (15 U.S.C. 632(a)(2)).

__ (ii) Alternate I (MAR 2020) of 52.219-28.

__ (23) 52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Mar 2020) (15 U.S.C. 637(m)).

__ (24) 52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Mar2020) (15 U.S.C. 637(m)).

__ (25) 52.219-32, Orders Issued Directly Under Small Business Reserves (Mar 2020)(15 U.S.C. 644(r)).

__ (26) 52.219-33, Nonmanufacturer Rule (Mar 2020) (15U.S.C. 637(a)(17)).

__ (27) 52.222-3, Convict Labor (Jun 2003) (E.O.11755).

__ (28) 52.222-19, Child Labor- Cooperation with Authorities and Remedies (Jan2020) (E.O.13126)

__ (29) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).

__ (30) (i) 52.222-26, Equal Opportunity (SEP 2016) (E.O.11246).

  __ (ii) Alternate I (FEB 1999) of 52.222-26.

__ (31) (i) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).

  __ (ii) Alternate I (JUL 2014) of 52.222-35.

__ (32) (i) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).

  __ (ii) Alternate I (JUL 2014) of 52.222-36.

__ (33) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C. 4212).

__ (34) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).

__ (35) (i) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O. 13627).

  __ (ii) Alternate I (MAR 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).

__ (36) 52.222-54, Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)

__ (37) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

  __ (ii) Alternate I (MAY 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.)

__ (38) 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (Jun 2016) (E.O. 13693).

__ (39) 52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (Jun 2016) (E.O. 13693).

__ (40) (i) 52.223-13, Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (OCT 2015) of 52.223-13.

__ (41) (i) 52.223-14, Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (Jun2014) of 52.223-14.

__ (42) 52.223-15, Energy Efficiency in Energy-Consuming Products (May 2020) (42 U.S.C. 8259b).

__ (43) (i) 52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).

  __ (ii) Alternate I (JUN 2014) of 52.223-16.

_ (44) 52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020) (E.O. 13513).

__ (45) 52.223-20, Aerosols (Jun 2016) (E.O. 13693).

__ (46) 52.223-21, Foams (Jun2016) (E.O. 13693).

__ (47) (i) 52.224-3 Privacy Training (JAN 2017) (5 U.S.C. 552 a).

  __ (ii) Alternate I (JAN 2017) of 52.224-3.

__ (48) 52.225-1, Buy American-Supplies (May 2014) (41 U.S.C. chapter 83).

__ (49) (i) 52.225-3, Buy American-Free Trade Agreements-Israeli Trade Act (May 2014) (41 U.S.C.chapter83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.

  __ (ii) Alternate I (May 2014) of 52.225-3.

  __ (iii) Alternate II (May 2014) of 52.225-3.

  __ (iv) Alternate III (MAY 2014) of 52.225-3.

__ (50) 52.225-5, Trade Agreements (Oct 2019) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).

__ (51) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

__ (52) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302Note).

__ (53) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov2007) (42 U.S.C. 5150).

__ (54) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov2007) (42 U.S.C. 5150).

__ (55) 52.229-12, Tax on Certain Foreign Procurements (JUN 2020).

__ (56) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).

__ (57) 52.232-30, Installment Payments for Commercial Items (Jan2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)_ (58) 52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct2018) (31 U.S.C. 3332).

__ (59) 52.232-34, Payment by Electronic Funds Transfer-Other than System for Award Management (Jul 2013) (31 U.S.C. 3332).

__ (60) 52.232-36, Payment by Third Party (May 2014) (31 U.S.C. 3332).

__ (61) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).

__ (62) 52.242-5, Payments to Small Business Subcontractors (Jan 2017) (15 U.S.C. 637(d)(13)).

__ (63) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).

  __ (ii) Alternate I (Apr 2003) of 52.247-64.

  __ (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

__ (1) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter67).

__ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May

2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (3) 52.222-43, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).

__ (4) 52.222-44, Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (May 2014) (29U.S.C.206 and 41 U.S.C. chapter 67).

__ (5) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).

__ (6) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).

__ (7) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).

__ (8) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).

__ (9) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, as defined in FAR 2.101, on the date of award of this contract, and does not contain the clause at 52.215-2, Audit and Records-Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(e)(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (JUN 2020) (41 U.S.C. 3509).

(ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).
(iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
(v) 52.219-8, Utilization of Small Business Concerns (OCT 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(vi) 52.222-21, Prohibition of Segregated Facilities (APR 2015).
(vii) 52.222-26, Equal Opportunity (SEP 2015) (E.O.11246).
(viii) 52.222-35, Equal Opportunity for Veterans (JUN 2020) (38 U.S.C. 4212).
(ix) 52.222-36, Equal Opportunity for Workers with Disabilities (JUN 2020) (29 U.S.C. 793).
(x) 52.222-37, Employment Reports on Veterans (JUN 2020) (38 U.S.C. 4212).
(xi) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (DEC 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
(xii) 52.222-41, Service Contract Labor Standards (Aug2018) (41 U.S.C. chapter 67).
(xiii) (A) 52.222-50, Combating Trafficking in Persons (JAN 2019) (22 U.S.C. chapter 78 and E.O 13627).
(B) Alternate I (Mar2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627).
(xiv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May2014) (41 U.S.C. chapter 67).
(xv) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (MAY2014) (41 U.S.C. chapter 67).
(xvi) 52.222-54, Employment Eligibility Verification (OCT 2015) (E.O. 12989).
(xvii) 52.222-55, Minimum Wages Under Executive Order 13658 (DEC 2015).
(xviii) 52.222-62, Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).
(xix) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
(B) Alternate I (Jan 2017) of 52.224-3.
(xx) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
(xxi) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (Jun 2020) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
(xxii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J LIST OF ATTACHMENTS

1. Statement of Objectives
    i. Appendix 1: Contract Deliverables

Statement of Objectives

Program Title: Rapid Acceleration of Diagnostics (RADx) – Tech
Project Title: Rapid Acceleration of Diagnostics (RADx) Program: Tech Project # 6114 Fluidigm – Advanta Dx SARS-CoV-2 RT-PCR Assay for Saliva
Agency: National Institute of Biomedical Imaging and Bioengineering (NIBIB) / National Institutes of Health (NIH)

1. Background

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has a requirement for proposals to provide up to $500 million across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. Rapid Acceleration of Diagnostics (RADx), is a fast-track technology development program that leverages the National Institutes of Health (NIH) Point-of-Care Technology Research Network (POCTRN). RADx will support novel solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. RADx is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

2. Purpose and Objectives

NIBIB is providing substantial support to accelerate the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improvements to clinical laboratory tests, that can directly detect SARS-CoV-2, the virus that causes COVID-19. NIBIB will support the full range of product development including commercialization and product distribution. The ultimate goal of the RADx program – across multiple projects/contracts – is to make millions of tests per week available to the American public, particularly those most vulnerable to and/or disproportionately impacted by COVID-19, in the late summer of 2020, and having even more tests available in time for the 2020–2021 flu season.

To meet the accelerated timelines, RADx has assembled a national network of expert technical, clinical, manufacturing, and regulatory advisors who will provide individualized assistance for project development and commercialization. Funding for projects selected for this program will be dependent on successfully meeting aggressive project milestones. Through the POCTRN grants, NIBIB provides financial and in-kind support to accelerate the entire product life-cycle, from design to market, for projects that meet milestones successfully. To ensure that innovations are available to the public as quickly as possible, NIH will leverage established partnerships with federal agencies, such as FDA, CDC, CMS, ASPR/BARDA, the Department of Defense, as well as commercial and private entities to propel technologies developed by RADx into widespread use.

The RADx program will consider innovations at all stages of readiness to circumvent current limitations to SARS-CoV-2 testing capacity, including:

- Early stage: transformative innovations based on novel testing strategies that have potential for major scale up
- Mid stage: technologies using novel testing strategies that have demonstrated capability but need further validation, regulatory approval, and scale up
- Advanced stage (RADx ATP): modification and optimization of existing SARS-CoV-2 testing approaches, including clinical laboratory tests, that can dramatically increase testing capacity. Note: This arm of the RADx program is addressed under a separate Acquisition Plan.

Design features might include technical innovations that:

- Improve analytical performance, e.g., sensitivity, specificity, dynamic range, limit of detection, reliability, accuracy, speed (time to test result) and throughput
- Enhance operational performance through, e.g., development of a patient- and user-friendly design, use of alternative sampling strategies (e.g., saliva, exhaled breath), integration with mobile-devices, designs for home-based use or strategies to overcome bottlenecks with current testing approaches
- Improve access and reduce the cost of testing.

3. Scope

RADx-Tech is a two-phase program. All applications undergo an intensive week-long risk assessment by a panel of expert technical, clinical, manufacturing, and regulatory advisors. If the proposed technology meets viability metrics, projects may be selected to enter phase one.

Phase one, performed under a separate funding mechanism, consists of an accelerated research and development program in which the awardee receives both financial support and in-kind services through RADx grant funding. This outcome of this work is a fully instantiated technology ready for clinical validation, regulatory authorization, production and commercialization.

Phase two, or Work Package 2, of the program, executed under this contract, includes completing the validation, approval, and production processes in order to deliver a viable product in a scaled up capacity to the U.S. public.

4. Performance Objectives (Required Results)

A. Contract recipients have completed major research and development efforts and are focused in phase two on completion of required clinical validation, preparation of regulatory submissions, scale-up of production capabilities, and preparation for full commercialization of their product – a testing technology. Every contract will encompass similar expectations and milestones concerned with:
   1. meeting regulatory requirements, resulting in regulatory authorization for sale and use of the test;
   2. instantiation of agreed-upon production capacity;
   3. meeting agreed-upon production goals; and
   4. implementation of an agreed-upon commercial strategy to bring the test to market in a timeframe that will impact the COVID-19 pandemic as soon as possible.

B. Contract funding in phase two is structured in order to reduce risk to the Government, and is dependent on achievement of specific milestones in the Schedule of Deliverables, according to the Payment Schedule.

C. The contractor must use a SARS-Cov-2 test with FDA EUA (or will have EUA near the time of award), indicating a combination of sensitivity, specificity, and usability appropriate to the intended use according to FDA and/or CDC guidance, as applicable.

D. The contractor must make the product available for a confidential independent regulatory/validation assessment. The independent assessor will be selected by the Government and specified in the contract.

E. The contractor must provide a risk mitigation plan for each identified risk and update and inform

NIH on any changes/newly identified risks in an ongoing manner.

5. Contract Type

The contract type is Firm Fixed Price.

6. Place of Performance

Place of Performance will be at the contractor's site(s).

7. Period of Performance

The period of performance of the contract is anticipated to be July 30, 2020 through July 29, 2021.

8. Deliverables/Delivery Schedule

See the attached Appendix 1: Schedule of Deliverables.

9. Other Requirements

A. The contractor must meet regularly (at least weekly) with NIH officials to update on progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion. When guided by NIH officials, the contractor must be willing to collaborate and cooperate under reasonable confidentiality terms with external organizations as needed to meet the contract goals in a manner which will not infringe contractor commercial or intellectual property rights.

No.	Objective Defined	Milestone Defined	Deliverable	Success Criteria	Est. Deliverable Due Date	Stage
1	(b)(4)					1
2						2
3						3
4						3
5						4
6						4
7						5
8						5

SubTasks

No.	Stage
A	1A
B **	1A
C	2A

From: Stevens, Ashley J [astevens@bu.edu]
Sent: 4/4/2017 4:11:42 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/O=NIH/OU=NIHEXCHANGE/cn=OD/cn=ROHRBAUM]
Subject: RE: data on university TT income
Attachments: Abrams, Leung and Stevens.pdf

One of mine, published in 2009 with the data from 2006.

> "How US Academic Licensing Offices are Tasked and Motivated – Is it all about the money?", Irene Abrams, Grace Leung and Ashley Stevens, Research Management Review, 17.1, Fall/Winter 2009;

Nothing since, but I have modeled it from the AUTM data once or twice – you have Net Income and can assume 25% kept for expenses. You have Net Patent Expenses. You have staffing numbers and can assume a mix and get salary levels from the AUTM salary survey, add 26% for overhead and 10% for all other office expenses. When you do that, the numbers look pretty similar to the 2006 data.

Best wishes,

Ashley Stevens
Focus IP Group, LLC
Winchester, MA

(b) (6)

From: Rohrbaugh, Mark (NIH/OD) [E] [mailto:RohrBauM@od.nih.gov]
Sent: Tuesday, April 4, 2017 11:42 AM
To: Stevens, Ashley J <astevens@bu.edu>
Subject: data on university TT income

Ashley:

The data you presented at KEI on the % of TTOs that cover costs and ranges of income was helpful. Is that in print somewhere or available from AUTM?

Thanks,
Mark

Mark L. Rohrbaugh, Ph.D., J.D.
Special Advisor for Technology Transfer
Director, Division of Technology Transfer and Innovation Policy
Office of Science Policy
Office of the Director
National Institutes of Health

Research Management Review, Volume 17, Issue 1
Fall/Winter 2009

How are U.S. Technology Transfer Offices Tasked and Motivated— Is It All About the Money?

Irene Abrams
Brandeis University

Grace Leung
Harvard University

Ashley J. Stevens
Boston University

ABSTRACT

We conducted a survey of directors of offices of technology transfer (TTOs) at U.S. academic institutions to determine how they are organized, tasked, financed, and motivated. We found some interesting quantitative data that have not been reported previously: (1) academic institutions spend on average 0.6% of their research budgets on transferring the technology resulting from their research programs, split 45% on patent protection and 55% on operating costs; and (2) over half the technology transfer programs bring in less money than the costs of operating the program, and only 16% are self-sustaining, bringing in enough income that, after distributions to inventors and for research, there are sufficient funds to cover the operating costs of the program. This leads to the surprising conclusion that the Bayh-Dole Act has been an unfunded mandate on academic institutions, and that academic institutions need to invest in their technology transfer operations in order to bring the benefits of their research to society.

We found that 20.3% of institutions are required to fund 50% or more of their operating budget from the income they generate, giving them an incentive to maximize income. The most important drivers of technology transfer are faculty service and translating the results of research, with only 11.5% reporting revenue maximization as the most important driver. We found that fewer than 20% of offices have incentive compensation plans, and only 28% of the performance factors that are taken into account in determining incentive pay are financial measures, with broader, non-financial performance measures accounting for 70% of the factors. Finally, a surprisingly large number of institutions do not have formal mission statements, but those that do establish broad, non-financial objectives for their offices, with only two institutions out of eighty (2.5%) having mission statements that establish revenue maximization as the objective of the offices.

We therefore conclude that although a small number of academic institutions have reaped very large rewards from their technology transfer activities—close to $4 billion in transactions that we were able to identify—these rewards appear to be a consequence of programs driven by broader objectives, and not a driving force for technology transfer as some have recently asserted. In our assessment, fewer than 10% of U.S. institutions' technology transfer programs are primarily motivated by financial return.

BACKGROUND—
TECHNOLOGY TRANSFER IN THE UNITED STATES

In 1980, Congress enacted the Bayh-Dole Act[1] and allowed U.S. universities, teaching hospitals, and research institutes to have the automatic right to take title to inventions developed with federal funding. In response, these institutions have established offices to seek patent protection on these inventions and license them to existing and new businesses for development and commercialization. Since 1991, the Association of University Technology Managers (AUTM) has published an annual survey that has quantified the magnitude of this enterprise[2].

The AUTM annual surveys have documented important products that have resulted from Bayh-Dole, and other studies have quantified the considerable contribution to improving public health through the discovery, patenting, licensing, and successful development of approaching 150 small molecule and biological drugs, vaccines, and *in vivo* diagnostics (Jensen et al., 2007). In addition, key components of the Internet economy—web browsers such as Internet Explorer, portals such as Lycos, email such as Eudora, and search engines such as Google—were based on licensed university technologies.

Certainly some institutions have garnered substantial economic returns from technology transfer. The 2008 AUTM Licensing Activity Survey showed that, overall, U.S. academic institutions received $3.4 billion in licensing income. However, as the survey results also show, this income is highly concentrated in a small number of institutions that have had one big success, most often a drug—the so-called "big hit". In a relatively recent phenomenon, some of these institutions have accelerated receipt of the future royalty streams from these "big hits" through a sale of their royalty rights to either the marketer of the drug or to specialized investment partnerships and have received even larger, one-time "big hits". Recent lump sum payments have approached $1 billion. Table 1 summarizes some of these transactions and shows that institutions and their inventors have received almost $3.5 billion from such sales since 1999, with the pace accelerating in recent years.

Table 1. Major Royalty Sales by Academic Institutions and/or Their Inventors

Date	**Product**	**Licensor**	**Amount** ($ million)	
June 1990	Neupogen	Amgen	$75	
Dec. 1999	Zerit	Yale University[1]	$125	
Jan. 2001	Thalomid	Children's Hospital	$5	
Sept. 2003	Aldurazyme	LA Biomed[2]	$25	
Jan. 2004	Neupogen/Neulasta (U.S.)	Memorial-Sloan Kettering[3]	$263	
Jan. 2005	Macugen	University of Colorado[4]	$45	
Jan. 2005	Rotarix	Children's Hospital Cincinnati[5]	n/a	**
Jan. 2005	Rotateq	Wistar Institute[6]	$45	*
July 2005	Emtriva	Emory University[7]	$525	
Aug. 2005	Remicade	NYU/Dr. Vilcek	$46	**
Aug. 2005	Neupogen/neulasta (Non-U.S.)	Memorial-Sloan Kettering[8]	$142	
Oct. 2005	Humira	Scripps Research Institute[9]	$32	*
June 2006	Embrel (US)	MGH[10]	$248	
April 2007	Enbrel (Foreign)	MGH[11]	$284	
May 2007	Remicade	New York University[12]	$650	
July 2007	FluMist	U. of Michigan[13]	$35	
Dec. 2007	Lyrica	Northwestern[14]	$700	
Dec. 2007	Rotarix	Cincinnati Children's Hosp.[15]	$24	
June 2008	RotaTeq	Children's Hosp. of Phil.[16]	$182	
	Total		$3,451	

* Estimate

** Sale by inventor

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[1] http://chronicle.com/weekly/v48/i06/06a02601.htm
[2] http://www.paulcapitalhealthcare.com/portfolio/overview.htm
[3] http://www.royaltypharma.com/media/pr/2004/MSKCC-01222004.pdf
[4] https://www.cu.edu/techtransfer/downloads/TechTransfer2005.pdf
[5] http://www.paulcapitalhealthcare.com/investmentcriteria/inventors/casestudies/cincinatti.htm
[6] http://webreprints.djreprints.com/1578940928144.html
[7] http://www.royaltypharma.com/media/documents/GileadSciencesandRoyaltyPharmaAnnounce525MillionAgreementwithEmoryUniversitytoPurchaseRoyalt.pdf
[8] http://www.royaltypharma.com/media/documents/RoyaltyPharmaAcquiresInternationalRoyaltyInterestinNeupogenandNeulasta.pdf
[9] http://www.scripps.edu/news/press/102605.html
[10] http://www.boston.com/business/technology/biotechnology/articles/2007/04/19/drug_nets_284m_for_mgh
[11] http://www.boston.com/business/globe/articles/2006/06/06/amgen_to_pay_mass_general_186m/
[12] http://www.royaltypharma.com/media/documents/Remicade-RoyaltyPharmaPurchaseofRemicadeRoyaltyFromNYU.pdf
[13] http://www.dricapital.com/show_info.php?page_id=28
[14] http://www.royaltypharma.com/media/documents/lyrica-royalty_pharma_purchase_of_lyrica_royalty_from_northwestern_university_december_18_2007.pdf
[15] http://www.paulcapitalhealthcare.com/newsroom/fundnews/012308.htm
[16] http://www.royaltypharma.com/media/documents/rotateq.pdf

Another source of "big hits" has been sales of equity, such as Dartmouth's $64 million sale of its equity stake in Medarex in 2000 and Stanford's sale of its $355 million equity stake in Google in 2005. Yet another has been legal settlements, such as the University of California's $200 million settlement with

Genentech over human growth hormone in 2000 and $30.4 million with Microsoft in 2007 over accessing interactive content on web pages, and the 1999 settlement between the University of Minnesota and Glaxo over Ziagen, valued at $300 million.

In spite, or perhaps because, of these financial successes, the involvement of academia in commercializing the results of its research has been controversial. Books written on the subject have blamed research commercialization for everything from increasing undergraduate tuition to destroying the public's trust in the objectivity of the advice and analysis it receives from professors (Bok, 2003; Krimsky, 2003, Washburn, 2005). Others, however, have documented the inherent entrepreneurialism of faculty (Shane, 2004), while others have demonstrated that only a minority of science faculty attempt to commercialize their research (Thursby & Thursby, 2003).

However, there has been little research on why institutions invest in the resources necessary to commercialize the results of their research. When university presidents speak publicly on the issue, they focus more on the public's right to see a return on the investment of their tax dollars in research grants via the availability of new products and services, rather than on the financial return that they might hope to see. For instance, Dr. Mary Sue Coleman, President of the University of Michigan, told the Annual Meeting of the Association of University Technology Managers in 2005 (Coleman, 2003):

> I think many people are often confused about why we are interested in technology commercialization, in nurturing start up companies, and in facilitating more patents and license agreements.
>
> It is not about the promise of future revenues that might be generated from this activity.
> You heard me correctly. It is not about the money.
>
> Of course, revenue generation serves as an incentive. But first and foremost, technology transfer must serve our core mission: sharing ideas and innovations in the service of society's well-being. In fact, at Michigan we expect to re-invest institutional gains back into technology transfer efforts. Revenue generation is NOT the ultimate goal. It is simply the means by which we can increase the transfer of new knowledge into the business sector.

A recent study by Litan, Mitchell, and Eddy of the Kauffman Foundation disputed Dr. Coleman's views and emphasized the role of financial incentive in technology transfer (Litan, Mitchell, & Reedy, 2007). The Foundation's website stated[4]:

> The emphasis among universities to reap big financial rewards through licensing and patenting innovation developed by research scientists is actually impeding the development of new technologies and may be masking the importance of other means of knowledge transfer.

The study went on to claim that universities are motivated in their technology transfer activities by the prospect of "the big hit". They stated:

> Where this has happened, it is because TTOs have been charged with concentrating too heavily on maximizing revenues from the licensing of university-developed intellectual property, rather than maximizing the volume of innovations brought to the marketplace.

Litan et al. described their research methodology as follows:

> We have spent the last several years discussing the role of TTOs with multiple university leaders and researcher-innovators.

As practitioners of technology transfer, Litan et al.'s conclusions did not comport with our experiences. One possible source for the discrepancy is that they appear not to have included in their discussions what is probably the most reliable source of information on what drives academic technology licensing offices—namely the leadership of those offices. While it certainly can be argued that technology transfer offices have a vested interest in preserving the status quo, it cannot be denied that they are a very important source of perspective on the subject, so we decided to carry out a systematic study to ascertain the role of various drivers of behavior in technology transfer decision-making, by surveying the individuals who lead those offices. As will become clear in this paper, Litan et al.*'s* conclusions do not comport with the findings of our research.

METHODOLOGY

We developed a survey instrument and implemented it in the SurveyMonkey system[5]. The questionnaire consisted of 17 questions that were a combination of multiple-choice questions and open-ended questions, some requesting quantitative data, some requesting qualitative information, and some requesting opinions. The questionnaire is available in the appendix.

We sent the survey, via email, to the Association of University Technology Managers' (AUTM) list of the most senior individual in each member institution who is responsible for technology transfer on a full time basis—the so-called "Director's List". The list is compiled from a number of sources:

- Self identification in AUTM's annual membership renewal process
- Self identification in registration for attendance at AUTM's annual meeting
- Identification by AUTM from the attendance list for the AUTM annual meeting

We applied to AUTM's Statistics and Metrics Committee for access to the Director's List, and our request was approved.

The list AUTM supplied to us was worldwide and contained some 702 entries. We first sorted it by country and then by institution, which yielded 425 entries ostensibly from the U.S. Inspection of the name of the institution or the individual's email address showed that 17 were in fact non-U.S. institutions and one was a for-profit corporation; for 16 institutions, two individuals were identified as the most senior licensing individual for the same campus at the same institution. In these cases, we selected one of the two by inspecting their respective job titles. This yielded 391 useable email addresses.

We launched the survey, via email invitation, on November 27, 2007. Reminders were sent, via email, on December 4, December 10, and December 12. Fifty-one responses were returned as "Undeliverable" or "I have retired". Therefore, 340 invitations to participate in the survey were presumably sent and received by the recipient.

A total of 165 usable responses were returned for a 48.5% response rate. Of these, 112 of the respondents replied to every question.

We downloaded the responses, sorted them by institution, and inspected the responses for duplicate responses from the same institution and campus and found none. When we observed obvious errors in the financial responses (for example, thousands instead of millions), we corrected them. In cases in which it was not clear what the respondent meant, we called the respondent to check the figure.

In this paper, we report the responses to every question and the number of responses received for each question. In the sections in which we looked for correlations between different types of performance and behavior, for consistency we analyzed only the 112 complete responses.

RESULTS

Respondents

Type of Institution

The first question asked was whether the respondent was a university, hospital, research institute or other. The results are shown in Table 2. The overwhelming majority of respondents were at universities.

Table 2. Type of Respondent

Type of Institution	Number	%
University	126	76.4%
Research Institute	23	13.9%
Hospital	14	8.5%
Federal Laboratory	2	1.2%
Total	165	

We next asked whether the institution was publicly owned or privately owned. The results are shown in Table 3. Publicly owned institutions made up more than 60% of the respondents.

Table 3. Ownership of Institutions

Ownership	Number	%
Private	63	38.2%
Public	102	61.8%
Total	165	

Organization of Offices

We then asked how the TTO was organized—whether it was an operating unit of the institution or an independent corporation such as a research foundation. The results are shown in Table 4. A total of 86% of the offices were organized as units of the institution and only 14% were separate corporations.

Table 4. Organizational Structure of Technology Transfer Offices

Organizational Structure	Number	%

Within Institution	142	86.1%
Independent corporation	23	13.9%
Total	165	

Of the 23 offices organized as independent corporations, all but one were associated with public institutions while one was associated with a private institution. Public universities are governmental entities and so are subject to certain contractual constraints. They frequently find it advantageous to assign ownership of and responsibility for licensing their intellectual property to a research foundation that is an independent 501(c)3 non-profit corporation and is not subject to the legal constraints of a governmental entity.

Finally, we asked how the office reported within the institution—through the academic side of the organization, i.e., ultimately to a Provost, or administratively, i.e., ultimately to a Vice President or Executive Vice President, or to an independent Board. The results are shown in Table 5. Reporting through the administrative side was somewhat more common, with a small proportion reporting directly to the President/Chancellor.

Table 5. Reporting Structure of Organizations

Reporting Structure	**Number**	**%**
Academic	55	33.7%
Administrative	81	49.7%
Independent Board	13	8.0%
Both/President/Chancellor	9	5.5%
Other	5	3.1%
Total	163	

Volume of Research Support

We asked the institutions to report the volume of their research. The total reported was $35.7 billion, which is 78.5% of the $45.4 billion in total research support that was indicated on the 2006 AUTM Licensing Activity Survey[6]. This demonstrates that our data are more representative of the totality of U.S. academic licensing activity than the 48.5% overall response rate would indicate. We note, however, that three federal laboratories reported to our survey—federal laboratories do not report to the AUTM Licensing Activity Survey.

Size of Technology Transfer Offices

We asked respondents to report the total employment of their offices, divided between professional staff and support staff. The total reported employment is shown in Table 6.

Table 6. Total Staffing of Reporting Institutions

Staff Category	**Number of FTEs**	**Number Reporting**
Professional Staff	729	153
Support Staff	587	134

Total	1,316

For comparison, respondents to the 2006 AUTM Licensing Activity Survey reported total employment of 1,831.7 FTEs, with support FTEs slightly exceeding professional FTEs. Respondents to our survey therefore employed 71.8% of the employment reported to AUTM, confirming the conclusion of the previous section that our data are more representative of total US technology transfer activity than the overall survey response rate would indicate.

For purposes of subsequent detailed analysis, we assigned size variables to institutions based on both the size of their total research expenditures and the basis of the total size of their technology transfer office. The cohorts and the number in each cohort are shown in Table 7.

Table 7. Cohort Definitions and Populations (Universities Only)

Cohort	**Research Expenditures ($ million)**	**Number in Cohort**	**Total FTEs**	**Number in Cohort**
Very Small	Up to $50	20	1–3	9
Small	$51–100	23	4–5	33
Medium	$101–250	45	6–10	42
Large	$251–500	24	10–24	36
Very Large	>$500	39	>25	34

Budgeting Process

The expenses of running a technology transfer office can be broadly divided between patent costs, normally spent externally, and personnel and other operating costs. We next asked respondents to tell us whether they had separate patent and operating budgets or were given a combined budget, implying they had the flexibility to spend their budget between the two categories as they saw fit. The results are shown in Table 8. A total of 60% of institutions had separate patent and operating budgets.

Table 8. Budgeting Procedures

Budget Procedure	**Number**	**%**
Separate Patent and Operating Budgets	78	60%
Combined Patent and Operating Budgets	53	40%
Total	131	

We next asked respondents how big their patent and operating budgets were. The totals for 114 institutions are shown in Table 9.

Table 9. Technology Transfer Budgets

Budget Category	**Amount**	**%**
Patent Budget	$93,636,000	44.2%
Operating Budget	112,838,500	53.3%
Unspecified	5,361,000	2.5%

Total	$211,835,500

Respondents reported spending roughly 20% more on operations—salaries, travel, services, etc.—than on patent protection. This is the first hard data that we've seen of the relative balance between personnel and legal expenditures in U.S. TTOs, though an extensive model developed by Brandt et al. based on staffing levels reported to the AUTM Survey combined with data from a number of surveys of technology transfer salaries (Brandt et al., 2005) came to a similar conclusion.

The 112 institutions that separately reported their operating budgets had total staffing of 925, implying an average operating cost per staff member of $121,988 annually.

For those institutions that reported their operating and patent budgets separately, we calculated the ratio of their patent budget to their operating budget. A ratio of 1:0 would indicate that an institution spent as much on patent protection as on operations. We found an extremely broad spread of values, reflecting an equally disparate spread of operating philosophies. As shown in Table 10, the range ran from a 6.4:1 ratio at one extreme[7] (though this was at an institution with a relatively low overall level of activity—$16k expenditures on patents and $3k on operations. The highest ratio at an institution with a substantial level of activity was 3.5:1—$700k on patents and $200k on operations) to a 0.092:1 ratio (expenditure of $60k on patents and $600k on operations) at the other extreme. The mean was 0.91:1.

Table 10. Variation in Ratio of Institutional Patent and Operating Budgets

Statistical Measure	**%**
Mean	91.9%
Median	60.0%
Std. Dev.	94.9%
Minimum	9.2%
Maximum	640.0%

Figure 1 shows the distribution of this ratio.

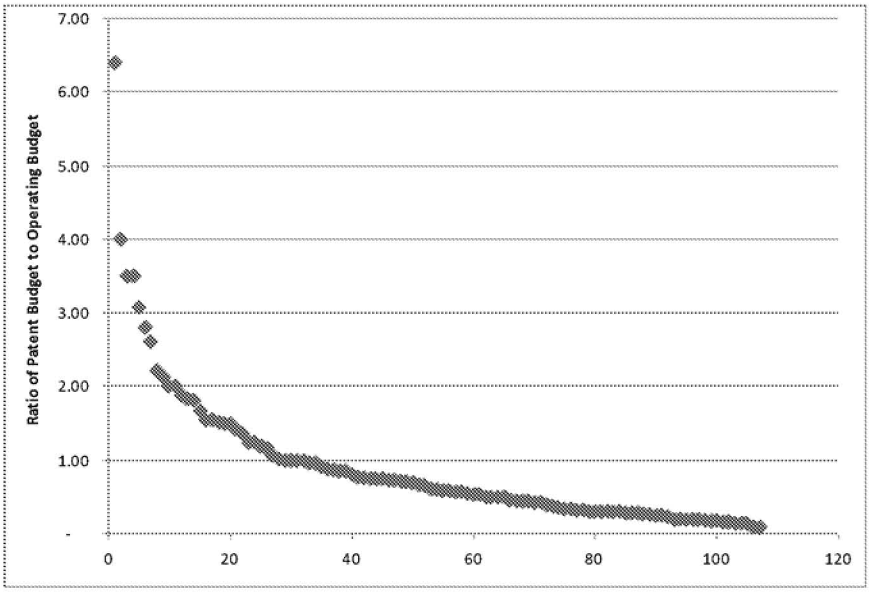


Figure 1. Ratio of Patent Budget to Operating Budget by Institution

The research budgets of the 116 institutions that reported their technology transfer budgets totaled $26.5 billion, implying that these institutions spend 0.59% of their research budgets on protecting and commercializing the results of that research.

As with the relationship between patent and operating expenditures, there is a considerable variation between institutions in the relationship between technology transfer expenditures and total research expenditures, from a high of 8% to a low of 0.01%. The distribution in this ratio is shown in Figure 2.

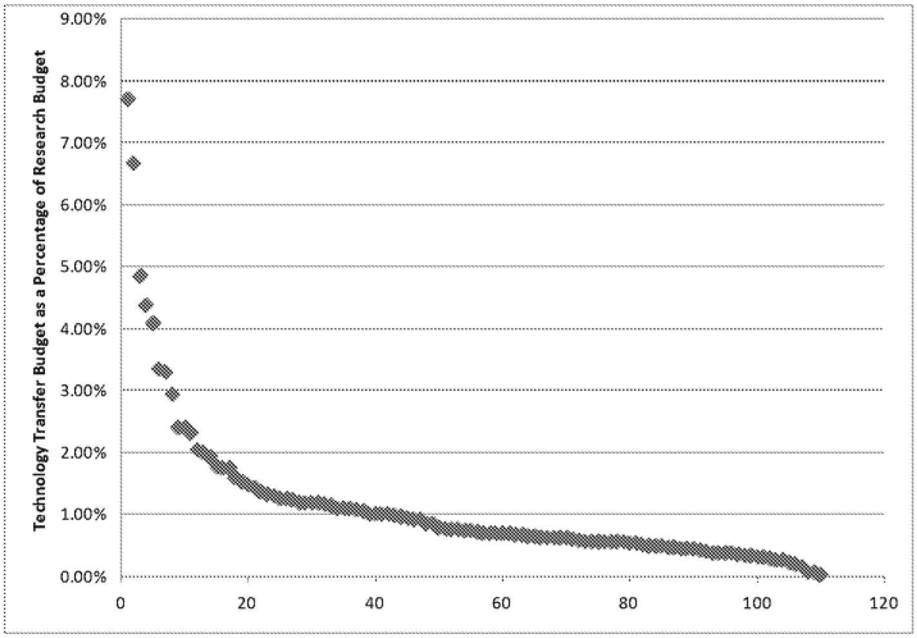


Figure 2. Technology Transfer Budget as a Percentage of Research Budget by Institution

Sources of Budget

Next we asked respondents how their technology transfer budgets were financed. One hundred and twenty six institutions reported the mechanism by which their budget was financed. The number of institutions reporting all or part of their budget coming from different sources is shown in Figure 3.

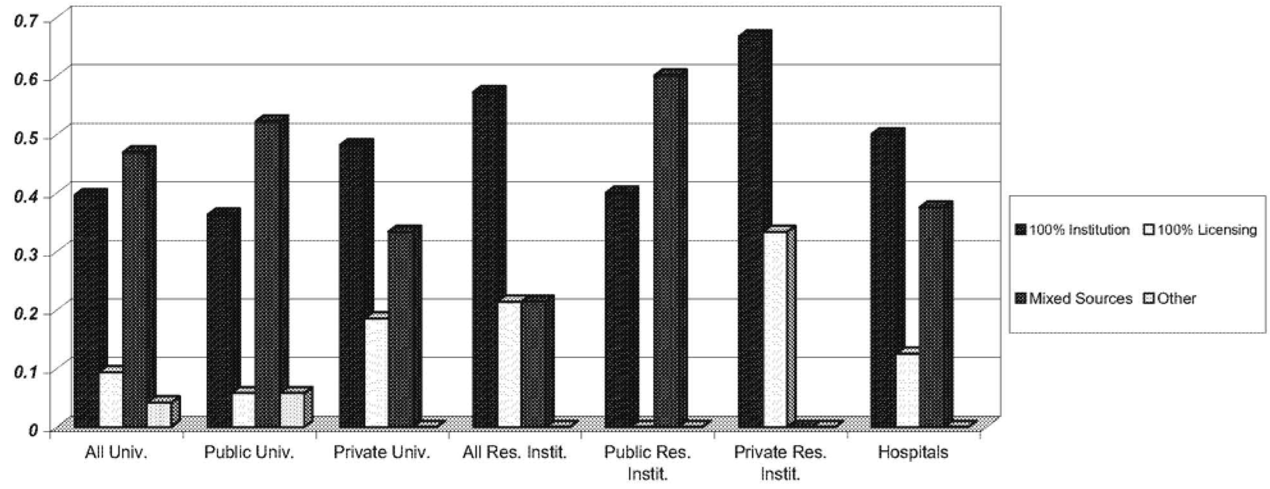


Figure 3. Sources of Technology Transfer Office Budget

This analysis shows that most TTOs receive their budget from a variety of sources. We found that 47% of universities receive part of their budget from the institution and part from licensing revenue. This reflects the reality (discussed in more detail below) that while many TTOs make money, few make enough to cover all of their expenses without some contribution from the institution. For Research Institutions, 57% are entirely funded by their institutions; at Hospitals, 38% are fully-funded by their institutions.

Factors Impacting How the TTO Budget is Financed

We examined the ways in which the source of the TTO budget correlated with the total research funding of the institution.

We found a very clear correlation between the size of a university's research budget and how its TTO is financed. As shown in Figure 4, at very small universities, over 60% of TTOs are entirely funded by the institution, while none are funded entirely by licensing income. In contrast, at large and very large universities, a significantly larger number of TTOs are funded entirely from licensing income, and relatively few are funded entirely by the institution.

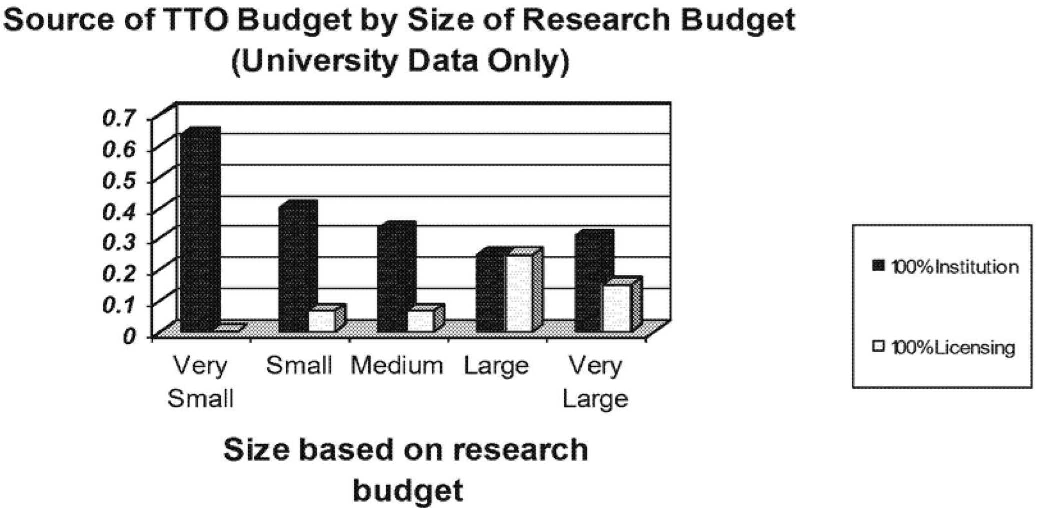


Figure 4. Source of TTO Budget by Size of University Research Budget

Operating Results

We did not ask for data on income generated by the offices from their licensing activities. However, we did ask respondents to report the financial contribution their office made to its institution.

As discussed by Brandt et al., the profitability of an office depends on the view taken of income. There are many claims on licensing income. As a requirement of Bayh-Dole, one portion of licensing income must be shared with inventors. The balance is required to be spent on research and education, which in practice means that part of the income is shared with some combination of the inventor's laboratory, department. and college to be spent on research, with the institution retaining only a portion to offset the operating costs of the office. The financial contribution of the technology transfer operation to the institution therefore depends on whether the calculation includes the portion of income that goes to the inventors, the portion of income that is distributed and spent on research, or just the portion that is retained to reimburse the patent expenditure and operating costs.

We therefore asked the institutions to characterize their financial performance as follows:

Category	Definition
Loss Making	Total expenses exceed total income
Gross Profitable	Total income exceeds total expenses
Net Profitable	Total income less distribution to inventors exceeds total expenses
Self-Sustaining	Total income less distribution to inventors, colleges/labs, provost, university etc. exceeds total expenses

The results are shown in Table 11. Over 50% lose money on their technology transfer operations, while only 16% are self-sustaining, retaining more from net income after distributions to inventors and for research than is spent on patent protection and operating costs. These results show that technology transfer is considerably less financially beneficial to institutions than was predicted by the Brandt et al. model, which predicted that only 42% were loss-making and that 30% of institutions were self-sustaining.

Table 11. Financial Contribution to Institution from Technology Transfer

Financial Contribution	Number	%
Loss making	68	52.3%
Gross profitable	27	20.8%
Net profitable	14	10.8%
Self sustaining	21	16.2%
Total	130	

Factors Impacting Profitability

We found that research institute TTOs were more profitable than those at universities and hospitals, and that private institutions were more likely to be profitable than public institutions, as shown in Figure 5.

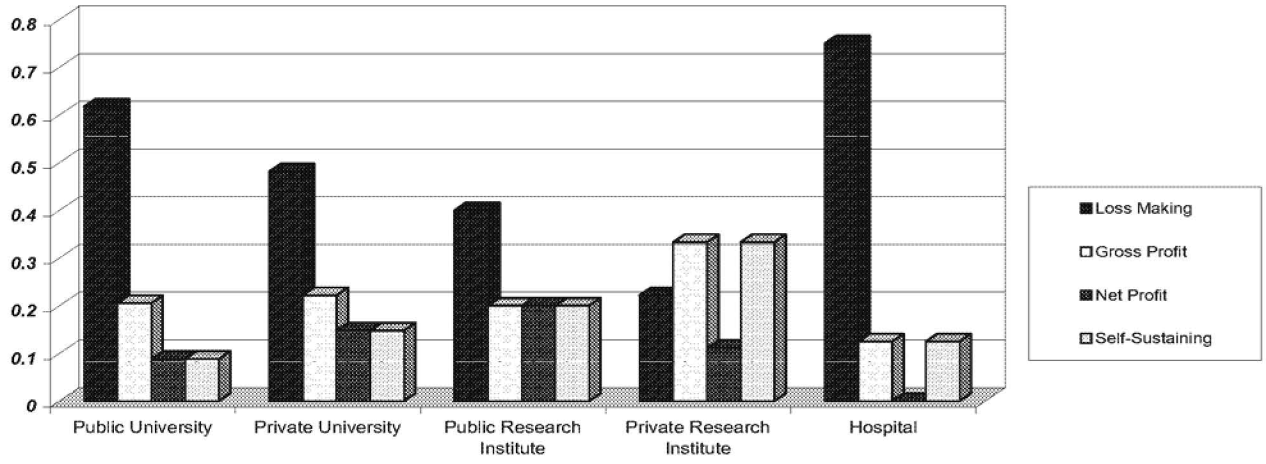


Figure 5. Profitability of TTOs by Institution Type

We found a direct correlation between the size of an institution's research budget and its profitability. The larger the research budget, the more likely the office was to be profitable, as shown in Figure 6. At very large schools, 15% are loss-making, and 31% are self-sustaining. By contrast, at very small schools, 76% are loss-making and none are self-sustaining. The relationship between size and profitability is almost linear—as the research budget of the institution increases, the profitability of the TTO increases.

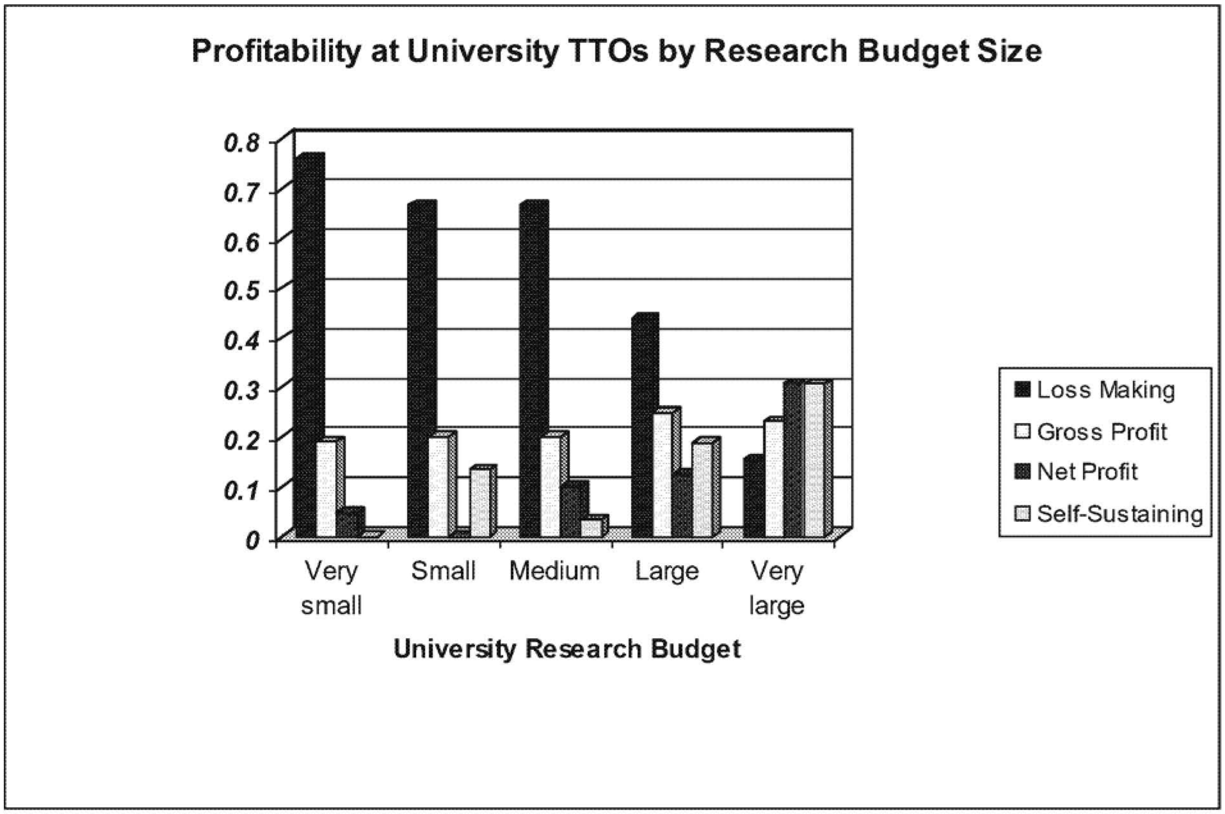


Table 6. Profitability of University TTOs by Research University Budget

We also looked at how the profitability of TTOs correlates with the size of the office. The results are shown in Figure 7. We found that the correlation between TTO profitability and office size closely follows the correlation between profitability and total research budget. None of the very large universities are operating at a loss, and none of the very small universities are self-sustaining.

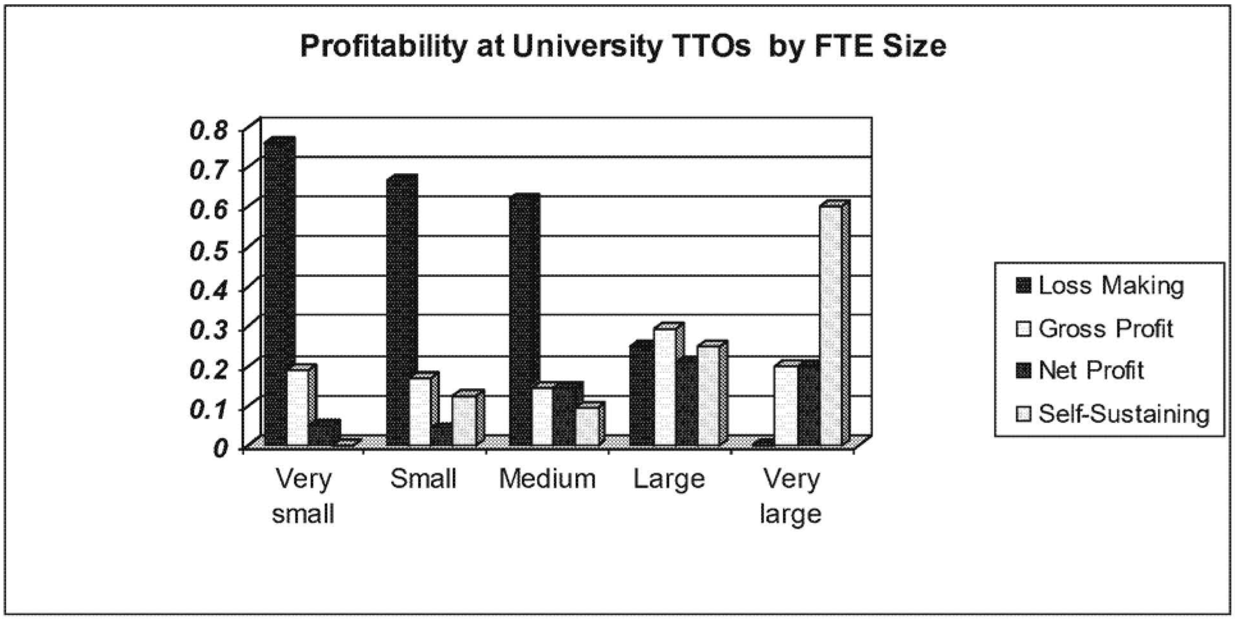


Figure 7. Profitability of University TTOs by FTE Size

This conclusion confirms the findings of Brandt et al., who found that the greater the age, FTE count, and research budget of a TTO, the more likely it was to be profitable. Further, they discovered that the TTOs of only those institutions that were 15 years old *and* had a research budget greater than $500 million *and* had a total staffing of 20 FTEs were all profitable—a very stringent set of conditions.

Reinforcing the relationship between staffing levels and profitability, a 2006 study by the Milken Institute (DeVol et al., 2006) went so far as to calculate that an incremental investment of $1 in TTO salaries would generate an additional $6 in license income.

We also looked at the relationship between reporting structure and profitability and found no significant correlation.

Drivers of Technology Transfer

The next section of the survey dealt with the informal drivers of technology transfer in an institution. By asking directors of TTOs for their rankings of the possible drivers of behavior, we hoped gain an understanding of how TTOs prioritize the forces shaping their behavior in their daily decision-making.

First, we asked the respondents what drives the TTO. Respondents were asked to rank six factors in order of priority from 1 to 6:

- Revenue maximization
- Faculty service
- Research results translation
- Industrial sponsored research income

- Risk management
- Other

Table 12 shows how many institutions ranked each factor as the most important driver of their office. Faculty service was ranked first most often, followed by translating research results. Maximizing revenue was ranked most important by only 11.5% of institutions.

We did not include "Economic Development" as an option, which anecdotally is reported to be a significant driving force at publicly owned institutions. This may explain the relatively high number of "Other" responses.

Table 12. Top-Ranked Drivers of Technology Transfer

Driving Factor	Number of Institutions Ranking Factor First	%
Faculty Service	51	39.2%
Translating Research Results	45	34.6%
Revenue Maximization	15	11.5%
Other	15	11.5%
Research Support	4	3.1%
Risk Management	0	0.0%
Total	130	

Factors Impacting Drivers of Technology Transfer

As shown in Table 13, the drivers were broadly similar for both universities and research institutions, with research results translation being the most important factor at research institutions while faculty service was most important at universities. At hospitals, research results translation was again the most important factor, while financial factors—revenue maximization and research support—were relatively more important than they were for universities and research institutions.

Table 13. Top-Ranked Driver of Technology Transfer by Type of Institution

Type of Institution	Top-Ranked Driver
Public Univ.	Faculty Service
Private Univ.	Faculty Service
Public Res. Inst.	Research Results Translation
Private Res. Inst.	Faculty Service
Hospital	Research Results Translation/Other

As shown in Figure 8, as the size of the university increases, the top driver changes from Faculty Service (over 60% in small and very small universities) to Research Result Translation (35% and 54%, respectively, at large and very large universities). The choice of Revenue Maximization as the top driver increases linearly from very small to large schools, but is not a factor at any very large schools. Industrially Sponsored Research Income was listed as the top driver at so few schools that we regarded it as not significant.

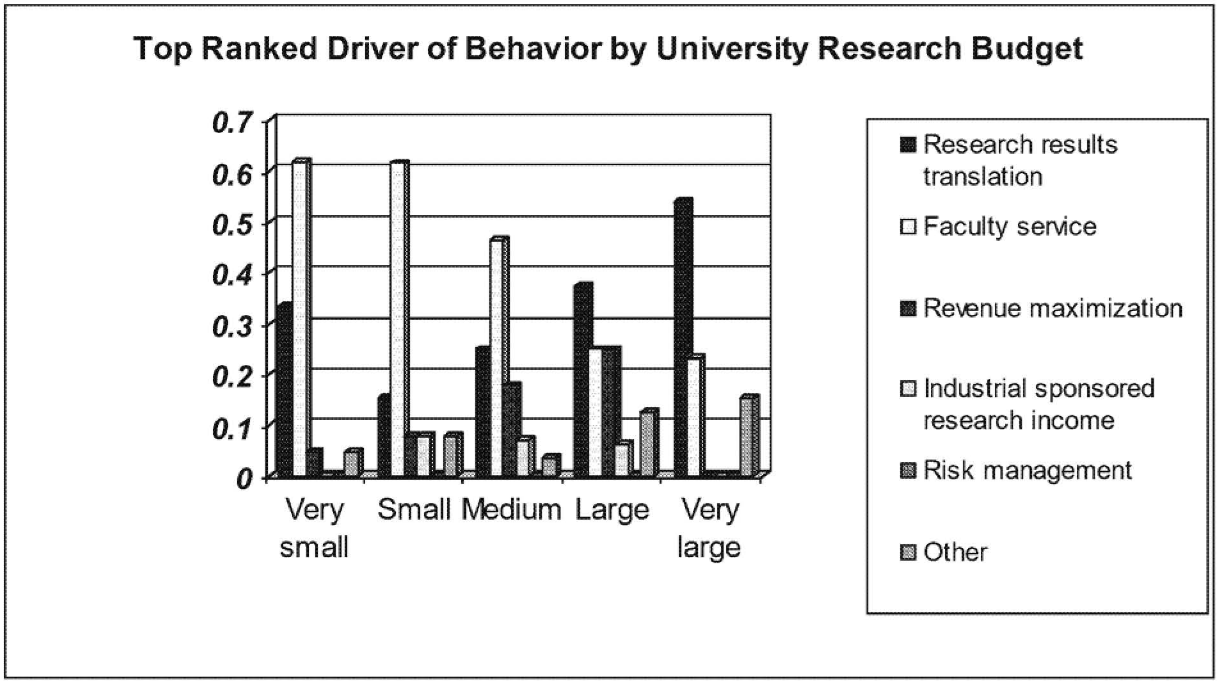

Top Ranked Driver of Behavior by University Research Budget

Figure 8. Top Ranked Driver of Behavior by University Research Budget

As shown in Figure 9, when we compared public and private universities, we found that Faculty Service is the top-ranked driver at a much higher rate at private universities than at public universities (56% vs. 41%, respectively), and Research Result Translation is chosen by a greater number of public universities than private universities (34% vs. 26%). Revenue Maximization was listed at the number one driver at 14% of public universities versus only 7% of private universities.

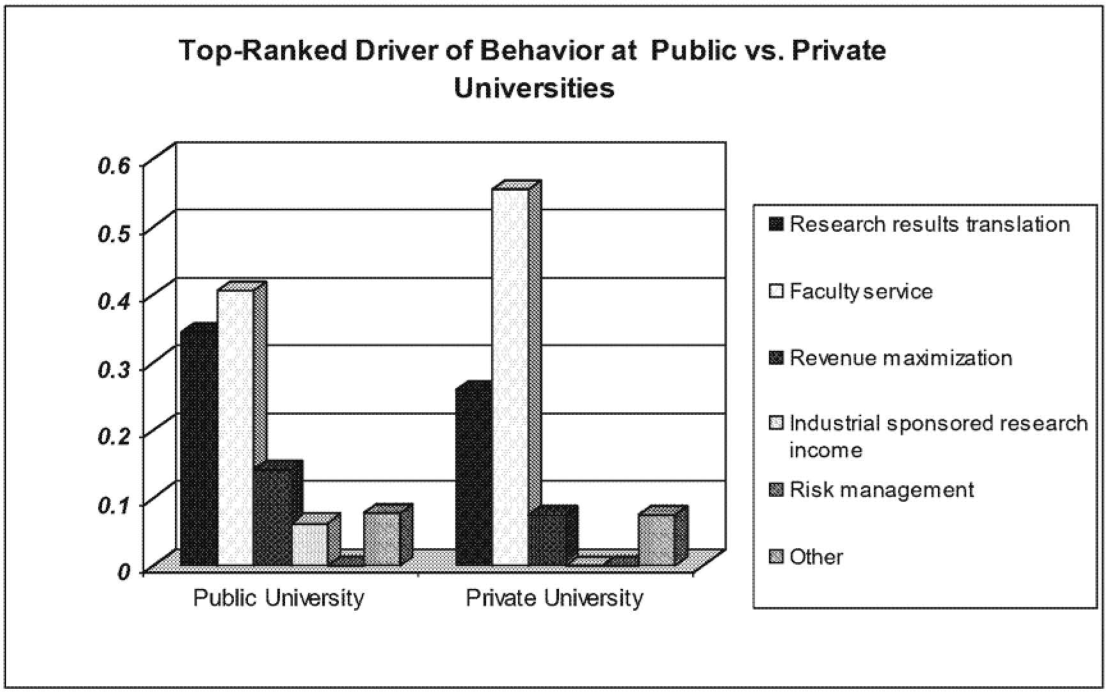


Figure 9. Top-Ranked Driver of Behavior at Public vs. Private Universities

As shown in Figure 10, when we looked at the top-ranked drivers of TTO behavior we found a steady decrease in the importance of faculty service to research results translation as total research expenditures increase.

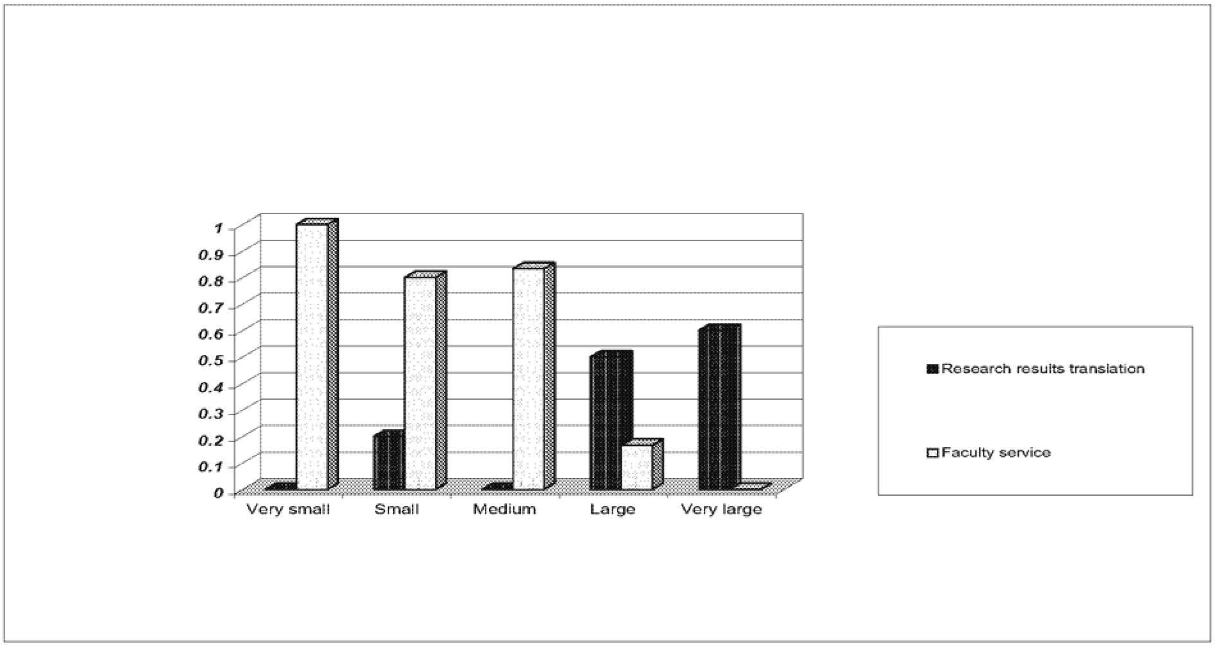


Figure 10. Effect of Research Budget Size on Top-Ranked Driver of Behavior

at Public Universities

We looked at whether the top driver of TTO behavior correlated with the organizational structure—i.e., do the priorities of the TTO change if the TTO reports to the administrative side of the university versus reporting to the academic side, and found no significant difference.

Finally, we examined whether having revenue maximization as the top driver of technology transfer translated into enhanced profitability. The results are shown in Table 14. There is no clear correlation between the two.

The results of these analyses show that an industry standard seems to have been adopted throughout the profession. Translating research results and providing a service to the faculty are clearly the primary drivers of TTO behavior, whether the TTO is large or small, private or public, or whether it is making money or losing money.

Table 14. Top Drivers of TTO Behavior Based on Profitability (All Institutions)

Profitability	No.	Research Result Trans.	Faculty Service	Revenue Max-imization	Industrial Sponsored Research	Risk Management	Other
Loss-Making	58	31%	45%	12%	9%	0%	7%
Gross Profit	24	33%	38%	8%	0%	0%	13%
Net Profit	12	33%	42%	25%	0%	0%	8%
Self-Sustaining	18	33%	39%	11%	0%	0%	17%
Total	112	32%	42%	13%	4%	0%	10%

Technology Transfer Office Mission

We next asked institutions if the technology transfer office has a formal mission statement. The results are shown in Table 15. A surprising number of offices do not have a formal mission statement.

Table 15. Technology Transfer Offices with a Formal Mission Statement

Formal Mission Statement	Number	%
Yes	75	58.6%
No	53	41.4%
Total	128	

We next asked those offices that have a formal mission statement to provide us with information on their mission statement. While only 75 institutions answered yes to this question, 80 submitted a copy of their mission statement.

The following are typical of the mission statements we received:

> The XXXX Office of Technology Transfer promotes and supports the research enterprise at the University by creating relationships with the private sector to develop, protect, transfer and commercialize research results for the public benefit.

> As a service provider, assist XXXX, its researchers, and its community partners with the development and promotion of biomedical innovations.
>
> - "Support the educational, research, and healthcare mission of the University by fostering creativity and innovation.
> - Initiate and sustain cooperation and collaboration between the University and business and industry.
> - Act as the University's intellectual property management and technology marketing arm.
> - Advance healthcare-related economic development for our state and the nation.
> - Support economic development through technology licensing."
>
> It is the mission of the TTO to encourage broad practical application of System research for public benefit; to encourage and assist those associated with the System in the protection, licensing and commercialization of their discoveries; to ensure the equitable distribution of royalties and other monetary benefits resulting from the commercial application of intellectual property; and to see that commercialization activities benefit the research, education and outreach missions of the System into the future.

We searched all of the mission statements for keywords such as "value", "income", "revenue", "financial return" and "maximize" that would speak to a focus on financial return. We found mission statements such as:

> Promoting the transfer of XXXX's life science & medical technologies for public use and benefit, while generating ***income*** to support campus research and education.
>
> Our mission is to help facilitate scientific research at the Institute, promote transfer of Institute basic research discoveries to the marketplace for the public benefit, and generate ***revenue*** for further research.
>
> - To facilitate the movement of Institute's inventions from research to application.
> - To create ***value*** in the inventions by protecting them with patents and ensuring Institute's ownership rights.
> - To commercialize Institute's intellectual property in accordance with Institute's mission and external granting agency guidelines (NIH, NSF, HHMI).
> - To generate ***revenue*** for Institute, its inventors and its continued research through commercial licensing.
> - To facilitate development of the local Biotechnology Industry and economy. *(emphasis added in each case)*

The term *financial return* did not occur in any of the mission statements, and the words *maximum* and *maximize* each occurred only once in each of two mission statements that were the only ones that seemed to establish maximizing financial value and return as the mission of the office.

> To ***maximize*** the ***value*** of XXXX's intellectual assets through the creation of novel and effective models for commercializing technology.

The essential mission of the Office of Technology Transfer is twofold:

(1) to promote the timely transfer of commercially valuable knowledge and inventions developed in the University to the businesses most capable of reducing them to practice and benefiting the economy of XXXX and the nation, and

(2) to return ***maximum value*** for such commercialization to the inventor/s and to the University in support of its continuing research enterprise, in a manner which upholds sound ethical, legal, and academic standards. The value of technology licensing for the University includes its benefits in providing incentive to faculty for research and invention as well as the dollars received for financing continuing University research activity. *(emphasis added in each case)*

Incentive Compensation

The final section of questions concerned incentive compensation. We first asked whether any personnel in the office receive incentive compensation. The results are shown in Table 16. Clearly only a minority of personnel receive bonuses.

Table 16. Offices in Which Some Personnel Receive a Bonus

Do Some Personnel Receive a Bonus	**Number**	**%**
Yes	22	17.2%
No	109	85.2%
Total	131	

Next we asked how many personnel in the office receive bonuses and compared the answer with the reported number of staff. The results are shown in Table 17. Clearly, in the relatively small number of offices that offer bonuses, bonuses tend to be offered broadly within the office.

Table 17. Availability of Bonuses within the Office

Number Receiving Bonus	**Number**	**%**
All	9	40.9%
More than the Professional Staff	3	13.6%
All Professional Staff	2	9.1%
Fewer than All Professional Staff	2	9.1%
One	6	27.3%
Total	22	

Next we asked how the bonuses were calculated. First we asked whether they were calculated based on office performance, individual performance, or a combination of the two. The results are shown in Table 18. Clearly, the most prevalent practice is to incentivize a combination of total office performance and individual performance.

Table 18. Basis for Computation of Bonuses

* One respondent answered "NO" to question about having an office bonus scheme, but then gave details of a bonus scheme—that it was available to all professional staff and that it was based on overall office performance.

Calculation Basis	**Number**	**%**
Individual performance	2	8.7%
Office performance	4	17.4%
Combination of office + individual	17	73.9%
Total	23*	

Finally, we asked for information on the bases on which bonuses are calculated. From a list of five specific factors, we asked whether each was taken into account in calculating bonuses and, in addition, allowed respondents to identify one of more "other" factors. Respondents could identify as many factors as were relevant to their experience.

To analyze the data, we first reviewed what was entered in the "other" column, and entered the count for the number of specific factors identified by respondents.

Twenty one of the 22 respondents who reported that they had an incentive compensation plan identified the factors taken into account in computing incentive compensation. The 21 respondents reported 81 factors that were taken into account. A statistical analysis of the responses is shown in Table 19. Both the mean and the median Incentive Compensation Plans took into account four factors, though several only took into account one factor and one plan took into account eight factors.

Table 18. Number of Factors Taken into Account in Calculating Incentive Compensation

Measure	**Value**
Mean	3.90
Median	4.00
Std. Dev.	2.57
Min	1.00
Max	8.00

As shown in Table 20, the most common factor taken into account in computing Incentive Compensation was "Other", followed by Total Income and Transactions Completed, followed by Disclosures Received.

Table 19. Factors Taken into Account in Awarding Incentive Compensation

Factor	**Number**	**%**
Other	18	22.2%
Total income	14	17.3%
Transactions completed	14	17.3%
Disclosures received	10	12.3%
Operating surplus	9	11.1%
Faculty satisfaction	9	11.1%
Start-ups formed	7	8.6%
Total	81	

The “Other” category included the following, several of which were cited by multiple respondents:

- Beneficial products and services introduced to society
- Community service
- Exclusive licenses
- Faculty education activities
- New revenue
- Overall university financial performance
- Performance against specific targets
- Regional economic impact

Only two of these factors—Total Income and Operating Surplus—are financial return-oriented and account for 28.4% of the factors cited, while the remaining 10 are oriented toward broader measures of technology transfer performance.

ANALYSIS AND DISCUSSION

Our methodology was designed to make four independent determinations of the behavior of technology transfer in an institution through four independent sets of questions:

- How is the office financed?
- What drives the office—i.e., what behavior is the office actually demonstrating?
- What are the office’s incentives based on—i.e., what behavior does the institution really want and is prepared to pay extra for?
- What is the official mission of the office—i.e., what behavior has the institution told the office it wants from it?

First, looking at the sources of the TTOs’ operating budget, we found that 20.3% of offices are required to generate between 50% and 100% of their operating budgets from their license income. These institutions clearly have an incentive to maximize the income they generate simply in order to stay in business.

Next, looking at the actual behavior the offices displayed, we found that the most important drivers of technology transfer were faculty service and translation of research results. Only 11.5% of offices stated that maximizing revenue was the most important driver of technology transfer.

Third, looking at the behavior the institution really wanted and was prepared to pay extra for to obtain, we found that fewer than 20% of institutions provided incentive compensation to their TTOs; among those that did, only 28% of the factors taken into account in determining incentive compensation focused on financial return, with the remainder focused on broader, non-financial measures of performance. This means that only 5.6% of offices were incented based on financial performance.

Finally, the most visible way to make income important is to put it in the TTO’s mission statement. While a surprisingly high percentage of TTOs had no formal mission statement, only 2 out of 80 institutions that did have a formal mission statement—2.5%—mentioned maximizing income or revenue in their mission statement. This proportion falls to 1.6% of the 128 institutions that gave either a "yes" or "no" answer to the question on whether they had mission statements.

The results of these four separate determinations are summarized in Table 21:

Table 20. Summary of Estimates of Extent to which Behavior is Driven by Income

Area of Investigation	Extent Driven by Income
Operating Budget	20.30%
Drivers	11.50%
Incentive Compensation	5.60%
Mission Statement	2.30%

CONCLUSION

The results of these four independent determinations were consistent in demonstrating that financial return is not the major factor in technology transfer organization and behavior, as is often posited. There is a very clear trend in our results and an obvious conclusion to be drawn from them, namely that the more visible the factor we used to determine TTO behavior, the lower the frequency with which we found income maximization to be the most important factor.

- The most indirect way of encouraging revenue maximization is to make the operating budget of the TTO dependent on the income it generates. This had the highest incidence—20.3% of TTOs were required to generate half or more of their operating budget from the income they generate.
- Also subtle were the priorities that the TTOs reported as driving their activities; here only 11.5% of TTOs reported that revenue maximization was their most important driver.
- Including revenue maximization as part of an incentive compensation program means that an institution has made a formal, senior-level determination that it wants the TTO to maximize revenue, and is a much more overt measure. We found revenue maximization accounted for only 5.6% of incentive compensation.
- Finally, the most visible and public statement of an institution's desire for its TTO to maximize revenue is to include revenue maximization in the TTO's mission statement. Only 2.3% of the mission statements we were sent included revenue maximization as one of the TTO's missions.

We therefore conclude that, depending on the visibility of the measure of what drives the TTO, from 2.3% to 20.3% of technology transfer activities are driven by financial considerations, with most activity being driven by broader objectives such as translation of research results and service to the faculty. Which of these four very different figures represents the "best" measure? The average of the four figures is 9.9%, which is reasonably close to the 11.5% of TTOs that reported revenue maximization as the primary driver of their activities. If someone wanted to summarize our findings in a Twitter, we would suggest, "Only 10% of technology transfer activity in the U.S. is driven by revenue maximization"—or perhaps its corollary, "90% of technology transfer activity in the U.S. is driven by social rather than revenue considerations."

We therefore respectfully disagree with the conclusions reached by Litan et al. discussed in detail earlier, in which they concluded that:

> …TTOs have been charged with concentrating too heavily on maximizing revenues from the licensing of university-developed intellectual property, rather than maximizing the volume of innovations brought to the marketplace (Litan et al., 2007, n.p.).

In our research we found the direct opposite—that translating the results of research and servicing faculty are the primary drivers of technology transfer offices.

We believe these results are not surprising in light of the way technology transfer is organized in the U.S. Fewer than 15% of TTOs are organized as independent corporations. An independent corporation can develop a culture that is quite distinct from that of the parent institution, whereas if the TTO is an integral part of the institution, it will inevitably share its culture. Outside the U.S., particularly in the UK and Australia, independent corporations tend to be the preferred TTO model. The extreme example of an independent corporation is Imperial Innovations, PLC, the technology transfer arm of Imperial College, London, which is an independent corporation that is publicly traded on the Alternative Investment Market of the London Stock Exchange[8]. Clearly, Imperial Innovations has a fiduciary responsibility to its shareholders to maximize its profits, and it can no longer hew to the university's charitable mission.

Finally, we confirmed an earlier study that found that for over half of institutions, technology transfer is actually a cost to the institution rather than a source of income and that only 16% of institutions ***retain*** enough of their income to reimburse all the costs of operating their TTOs, after sharing their income with various stakeholders, such as inventors, labs, and the university.

We therefore predict that institutions which established their TTOs in the expectation of a "big hit" are likely to be disappointed; however, institutions that establish their offices with a broad set of goals will likely see their objectives realized.

We should conclude with a caveat. The above findings and conclusions should not be interpreted as implying that TTOs do not care about the financial terms of the license transactions they negotiate and will "give" the technology away. Far from it. Technology transfer offices have a strong sense of fairness and will fight hard to ensure that their institution shares fairly in the fruits of success if their technology is successful in the marketplace. Rather, our conclusions mean that income is not the primary motivator of offices; technologies with smaller market potential will receive as much attention as those that serve large markets; if there is a single, credible potential licensee interested in a technology, then the office will negotiate exclusively with that company rather than seeking additional licensees to create a competitive bidding situation; junior faculty will receive as much attention as senior faculty; and non-financial, academic and social considerations will be taken into account in negotiating deals.

Public Policy Implications

Although it was not one of the objectives of our research, our study has important public policy implications for the role of academic research in innovation ecosystems, both in the U.S. and globally. The Bayh-Dole Act was intended to break down the Chinese walls that had grown up between academic and corporate research and to integrate academic innovation into the U.S.'s innovation ecosystem. While it is beyond the scope of this article to discuss the economic impact of Bayh-Dole, studies have shown that it has succeeded admirably in this regard (Bayh, Allen, & Bremer, 2009; Jensen et al., 2009; Roessner et al., 2009). However, our study leads to the surprising conclusion that Bayh-Dole has turned out to be an unfunded mandate on U.S. academic institutions.

Bayh-Dole provided no direct funding for the technology transfer activity it was about to trigger. It was anticipated that the costs of technology transfer would be included in each institution's indirect cost base and that, subsequently, licensing income would rise to cover the costs of the activity. Two factors changed this expectation:

1. The administrative component of indirect costs was capped at 26% in the early 1990s—IDC no longer covers the complete costs of carrying out research. A recent study found that U.S. patent costs are only included in the IDC base at three U.S. academic institutions.
2. Equally, licensing income has not grown fast enough to cover the cost of the technology transfer function at most institutions, for several reasons (Stevens, 2003).

Licensing income grew slowly for several reasons. First, it took time for academic institutions to establish TTOs. The AUTM Annual Licensing Survey shows that the first wave of technology transfer offices were created fairly evenly over a thirteen-year period centered on 1990 (running from 1983 to 1996), not immediately after the passage of Bayh-Dole in 1980. TTOs continued to be created after 1996, albeit at a much slower rate, though there was another spike of start-ups in 1999 and 2000. Next, once TTOs were established, it took time to recruit and train staff, for a culture of technology transfer to develop on campuses, and for a portfolio of licensable inventions to develop. Then, because academic inventions are generally very embryonic and leading (bleeding?) edge, it generally takes from one to four years to find a licensee to make a commitment to develop a technology. And finally, since the majority of the most valuable academic inventions have been drugs, they have had to go through the 10- to 15-year clinical testing and FDA approval process.

The next issue is that few licenses generate substantial income. AUTM data show that only around 1% of licenses generate more than $1 million in income in any given year[9]. While this may sound substantial, a typical TTO would distribute around $750,000 of the $1 million to inventors and for research and only retain around $250,000 to cover TTO patenting and operating costs. The data in Table 1 shows that the incidence of the truly "big hits" is even more unevenly distributed and is primarily concentrated in a relatively small number of institutions that have created important drugs and vaccines.

Finally, only a relatively small amount of license income is used to offset the costs of technology transfer. At most institutions, 60–75% of income is distributed to the inventors to incentivize them to participate in the technology transfer process, and to laboratories and colleges to be spent on further research.

This issue also has implications outside the U.S. Over the past decade, many countries, initially in Europe and now in developing countries, have adopted the institutional ownership model of academic invention management pioneered by Bayh-Dole. Many have recognized this financial dilemma and have provided funding to kick-start the process. However, most have made the same assumption that the U.S. Senate did, and have provided funding for only relatively short periods of time—typically five years. Normally the TTOs are still well short of self-sustainability when the funding runs out and difficult decisions then have to be made.

We conclude, therefore, that new funding models for technology transfer are needed, both domestically and outside the U.S.

AUTHORS' NOTE

We thank the Association of University Technology Managers for providing us with access to its Directors List, and Janine Anderson, Boston University, for her meticulous proof-reading of the manuscript.

END NOTES

1. P.L. 96-517, Patent and Trademark Act Amendments of 1980; see, for instance, http://www.autm.net/aboutTT/aboutTT_bayhDoleAct.cfm
2. http://www.autm.net/about/dsp.licensing_surveys.cfm
3. http://www.paulcapitalhealthcare.com/newsroom/fundnews/012308.htm
4. http://www.kauffman.org/items.cfm?itemID=786, accessed 12/22/07.
5. http://www.surveymonkey.com/
6. http://www.autm.net/about/dsp.pubDetail2.cfm?pid=41
7. One institution reported a patent budget of $600k and an operating budget of only $37k despite reporting two professional and one support FTE. It appears that they misunderstood the question and reported only their "All other" budget and not their total operating budget, and we did not include these data.
8. Imperial College owns 51% of the company's stock.
9. For instance, the 2008 U.S. Annual Licensing Activity Survey found that of 15,498 licenses that were generating income, including 7,917 licenses that were generating running royalties (i.e., had advanced to a marketed product), only 192 licenses generated more than $1 million in income.

LITERATURE CITED

Bayh, B., Allen, J., & Bremer, H. (2009). Universities, inventors and the Bayh-Dole Act. *Life Sciences, Law and Industry Report, 24*(3), 1–5.

Bok, D. (2003). *Universities in the marketplace : The commercialization of higher education*. Princeton, NJ: Princeton University Press.

Brandt, K. D., Stevenson, E. J., Anderson, J. B., Ives, C. L., Pratt, M. J., & Stevens, A. J. (2005). Do most universities lose money on their technology transfer activities? Annual Meeting, Association of University Technology Managers, Phoenix, AZ.

Coleman, M. S. (2005). Address before the Annual Meeting, Association of University Technology Managers, Phoenix, AZ.

DeVol, R., Bedroussian, A., Babayan, A., Frye, M., Murphy, D., Philipson, T. J., Wallace, L., Wong, P., & Yeo, B. (2006). *Mind to market: A global analysis of university biotechnology transfer and commercialization.* Santa Barbara, CA: Milken Institute (available at: http://www.milkeninstitute.org/pdf/mind2mrkt_2006.pdf

Jensen, J., Wyller, K., London, E. R., Chatterjee, S. K., Murray, F. E., Rohrbaugh, M. L., & Stevens, A. J. (2007). *The role of public sector research in the discovery of new drugs*. Annual Meeting, Association of University Technology Managers, San Francisco, CA.

Jensen, J., Wyller, K., London, E. R., Chatterjee, S. K., Murray, F. E., Rohrbaugh, M. L., & Stevens, A. J. (2009). *The contribution of public sector research to the discovery of new drugs.* Paper presented at BIO Technology Transfer Symposium, San Francisco, CA.

Krimsky, S. (2003). *Science in the private interest: Has the lure of profits corrupted biomedical research?* Lanham, MD: Rowman & Littlefield.

Litan, R. E., Mitchell, L., & Reedy, E. J. (2007). Commercializing university innovations: Alternative approaches. Paper online via the Social Science Research Network, and on the *Issues in Science and Technology* web page: http://www.issues.org/23.4/litan.html.

Roessner, D., Bond, J., Okubo, S., & Planting, M. (2009). *The economic impact of licensed commercialized inventions originating in university research, 1996–2007.* Report to the Biotechnology Industry Organization, Washington, DC.

Shane, S. A. (2004). Academic entrepreneurship: University spinoffs and wealth creation. New York: Edward Elgar.

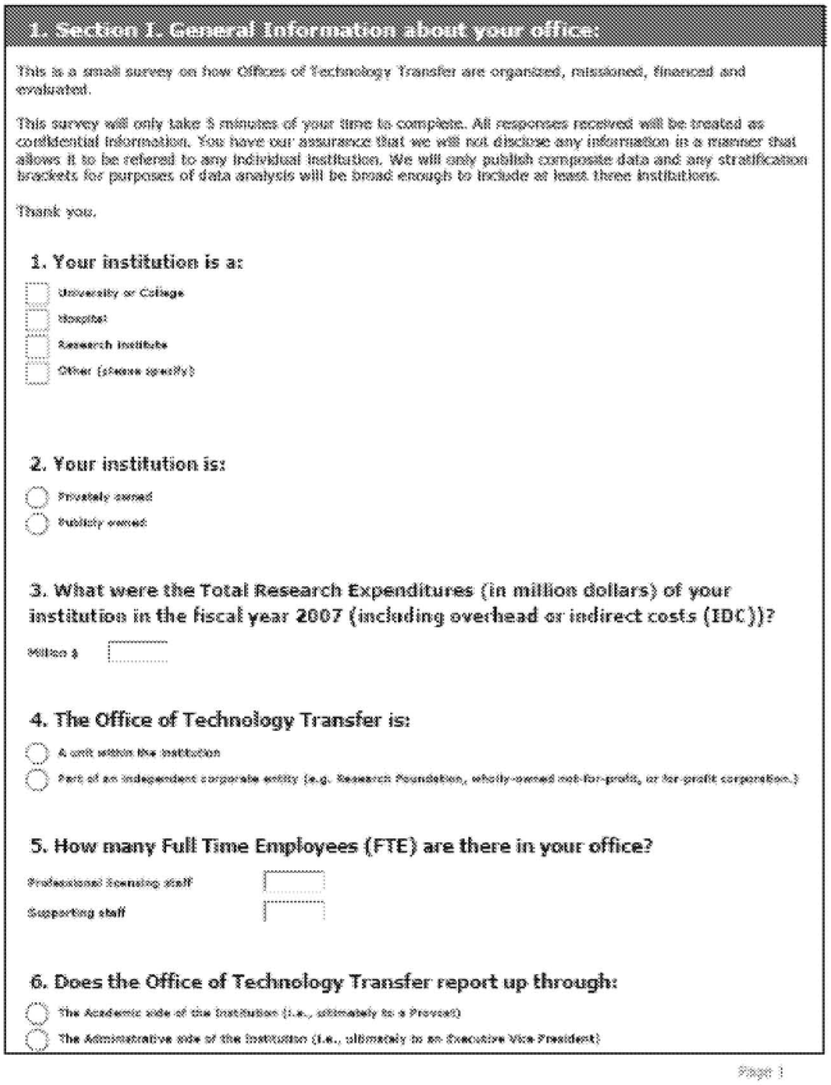
Stevens, A. (2003). 20 years of academic licensing – Royalty income and economic impact. *Journal of the Licensing Executives Society International (Les Nouvelles), 38,* 133–140.

Thursby, J. G., & Thursby, M. C. (2003). *Patterns of research and licensing activity of science and engineering faculty.* Atlanta, GA: Georgia Institute of Technology.

Washburn, J. (2005). *University, Inc.—The corporate corruption of American higher education*. New York: Basic Books.

Appendix

Questionnaire



1. Section I. General Information about your office:

This is a small survey on how Offices of Technology Transfer are organized, missioned, financed and evaluated.

This survey will only take 5 minutes of your time to complete. All responses received will be treated as confidential information. You have our assurance that we will not disclose any information in a manner that allows it to be refered to any individual institution. We will only publish composite data and any stratification brackets for purposes of data analysis will be broad enough to include at least three institutions.

Thank you.

1. Your institution is a:

☐ University or College
☐ Hospital
☐ Research Institute
☐ Other (please specify)

2. Your institution is:

○ Privately owned
○ Publicly owned

3. What were the Total Research Expenditures (in million dollars) of your institution in the fiscal year 2007 (including overhead or indirect costs (IDC))?

Million $ ☐

4. The Office of Technology Transfer is:

○ A unit within the institution
○ Part of an independent corporate entity (e.g. Research Foundation, wholly-owned not-for-profit, or for-profit corporation.)

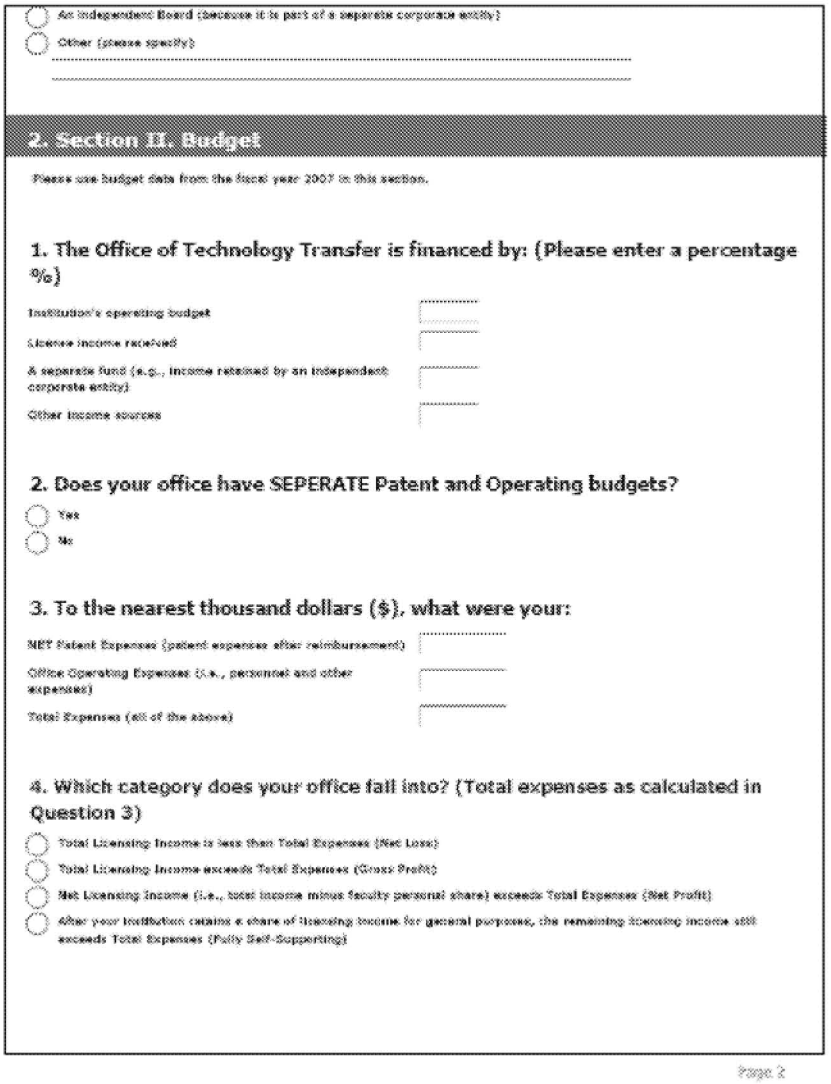
5. How many Full Time Employees (FTE) are there in your office?

Professional licensing staff ☐
Supporting staff ☐

6. Does the Office of Technology Transfer report up through:

○ The Academic side of the Institution (i.e., ultimately to a Provost)
○ The Administrative side of the Institution (i.e., ultimately to an Executive Vice President)

Page 1



○ An independent Board (because it is part of a separate corporate entity)
○ Other (please specify)

2. Section II. Budget

Please use budget data from the fiscal year 2007 in this section.

1. The Office of Technology Transfer is financed by: (Please enter a percentage %)

Institution's operating budget	
License income received	
A separate fund (e.g., income retained by an independent corporate entity)	
Other income sources	

2. Does your office have SEPERATE Patent and Operating budgets?

○ Yes
○ No

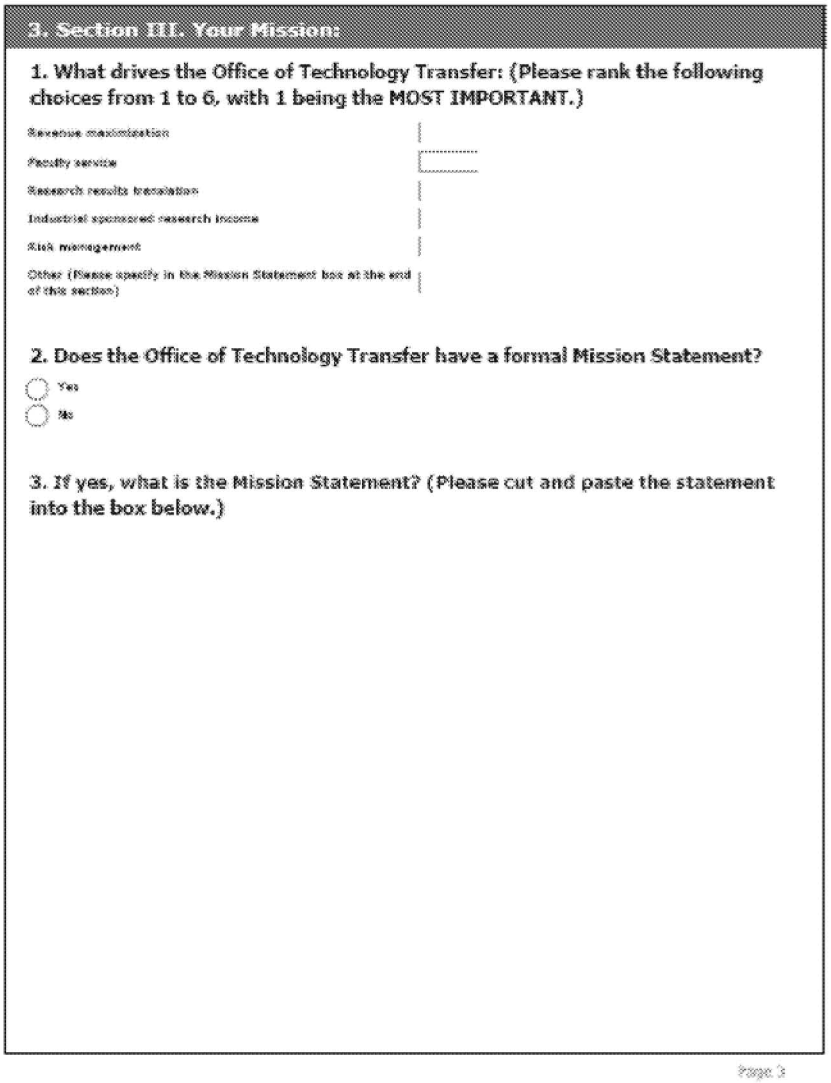
3. To the nearest thousand dollars ($), what were your:

NET Patent Expenses (patent expenses after reimbursement)	
Office Operating Expenses (i.e., personnel and other expenses)	
Total Expenses (all of the above)	

4. Which category does your office fall into? (Total expenses as calculated in Question 3)

○ Total Licensing Income is less than Total Expenses (Net Loss)
○ Total Licensing Income exceeds Total Expenses (Gross Profit)
○ Net Licensing Income (i.e., total income minus faculty personal share) exceeds Total Expenses (Net Profit)
○ After your institution retains a share of licensing income for general purposes, the remaining licensing income still exceeds Total Expenses (Fully Self-Supporting)

Page 2



3. Section III. Your Mission:

1. What drives the Office of Technology Transfer: (Please rank the following choices from 1 to 6, with 1 being the MOST IMPORTANT.)

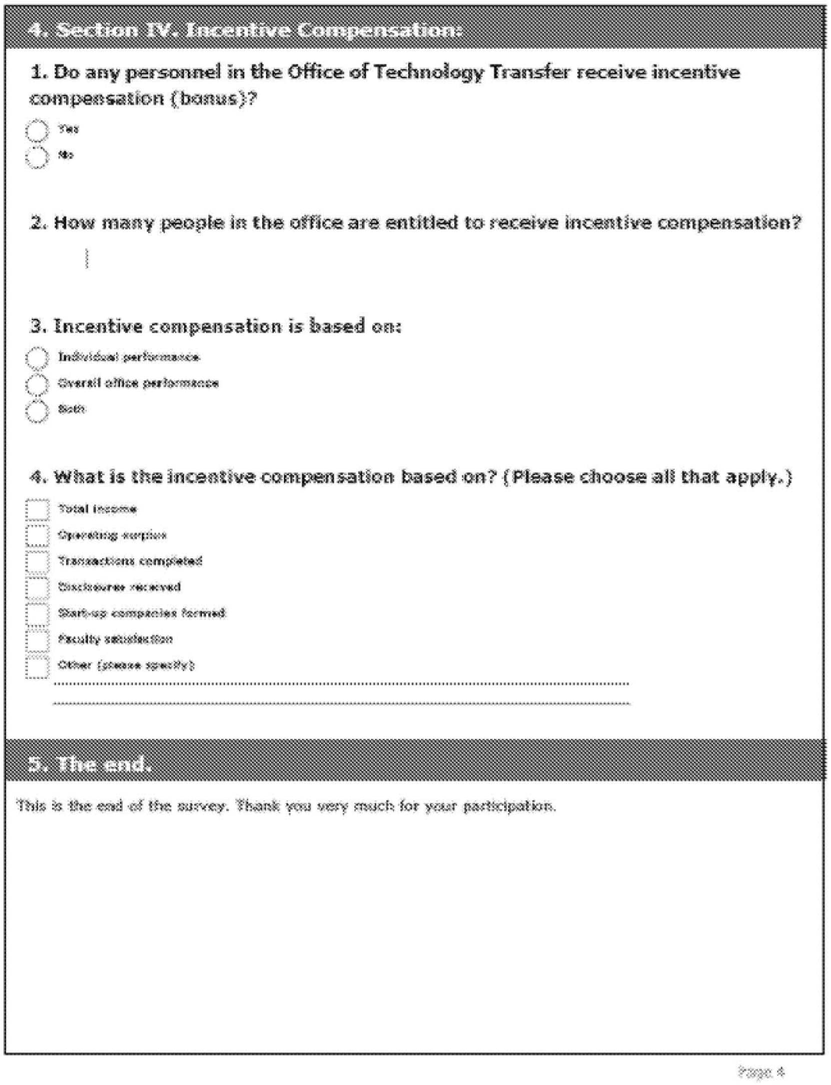
Revenue maximization
Faculty service
Research results translation
Industrial sponsored research income
Risk management
Other (Please specify in the Mission Statement box at the end of this section)

2. Does the Office of Technology Transfer have a formal Mission Statement?

○ Yes
○ No

3. If yes, what is the Mission Statement? (Please cut and paste the statement into the box below.)

Page 3



4. Section IV. Incentive Compensation:

1. Do any personnel in the Office of Technology Transfer receive incentive compensation (bonus)?

○ Yes
○ No

2. How many people in the office are entitled to receive incentive compensation?

3. Incentive compensation is based on:

○ Individual performance
○ Overall office performance
○ Both

4. What is the incentive compensation based on? (Please choose all that apply.)

☐ Total income
☐ Operating surplus
☐ Transactions completed
☐ Disclosures received
☐ Start-up companies formed
☐ Faculty satisfaction
☐ Other (please specify)

5. The end.

This is the end of the survey. Thank you very much for your participation.

Page 4

ABOUT THE AUTHORS

Irene Abrams is Executive Director of the Office of Technology Licensing at Brandeis University. Before joining Brandeis, she was a senior technology licensing officer at the Massachusetts Institute of Technology (MIT) and the Whitehead Institute. She is a founder of T3, an organization of small technology-transfer offices in New England. She also serves as president of the Massachusetts Association of Technology Transfer Offices. She holds a bachelor's degree from the University of Pennsylvania, a master's degree from Johns Hopkins University, and was a doctoral student at MIT.

Grace Leung is a Business Development Associate in the Office of Technology Development at Harvard University. Prior to joining Harvard, she was an intern at the Office of Technology Licensing at Brandeis University. She holds a Bachelor of Science and a Master of Philosophy in Biology from the Chinese University of Hong Kong, and a Doctor of Philosophy in Molecular Biology and Microbiology from the Tufts University Sackler School of Graduate Biomedical Sciences.

Ashley Stevens is Special Assistant to the Vice President of Research at Boston University and was previously Executive Director, Technology Transfer in the Office of Technology Development. He is also Senior Research Associate in the Institute for Technology Entrepreneurship and Commercialization in Boston University's School of Management, where he teaches two graduate-level, inter-disciplinary courses on technology commercialization. Before joining Boston University, he was Director of the Office of Technology Transfer at the Dana-Farber Cancer Institute, a teaching affiliate of the Harvard Medical School. Prior to entering the technology transfer profession, Dr. Stevens worked in the biotechnology industry for nearly ten years and founded two companies. He started his career with the Procter & Gamble Company. He is President of the Association of University Technology Managers (AUTM) and was previously its Vice President, Annual Meeting and Surveys. He was the recipient of the Bayh-Dole Award at AUTM's 2007 Annual Meeting. He is also active in the Licensing Executives Society, the Massachusetts Association of Technology Transfer Offices, which he co-founded, and the Massachusetts Biotechnology Council. Dr. Stevens holds a Bachelor of Arts in Natural Sciences, a Master of Arts and a Doctor of Philosophy in Physical Chemistry from Oxford University. He is a Certified Licensing Professional.

From: Wertz, Jennifer (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1E6CB9797CEF40F1B40E777AFE3795D7-WERTZJ]
Sent: 10/4/2018 9:32:39 PM
To: Rohrbaugh, Mark (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591ab6b2424b4b8997082718cbb29fab-rohrbaum]
Subject: Re: Voice Mail (24 seconds)
Attachments: 978-1-68083-401-7.pdf

Here you go. Looks like you have to first log in and the click the link to the book in the email.

Let me know if this doesn't work and I'll try again when I get home. Haven't tried doing attachments from the new email phone app yet.

Have a good trip.

Jenn

-------- Original Message --------
From: "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>
Date: Thu, Oct 4, 2018, 5:20 PM
To: "Wertz, Jennifer (NIH/OD) [E]" <wertzj@od.nih.gov>
Subject: Voice Mail (24 seconds)

Hi Jenn it's Mark I had logged into the now publishers dot com website.

And I'm showing up it's showing logged and with your user name but I don't see where you can download -- anything so -- if you could give me a call.

Thanks bye.

Preview provided by Microsoft Speech Technology. Learn More...

You received a voice message from Rohrbaugh, Mark (NIH/OD) [E] (Work) at 3014354485.

Caller-Id:	3014354485
Job Title:	Director
Company:	NIH
Work:	301.435.4485
Mobile:	(b) (6)
Email:	rohrbaum@od.nih.gov

Measuring Science, Technology, and Innovation: A Review

Measuring Science, Technology, and Innovation: A Review

Bronwyn H. Hall
University of California at Berkeley,
USA and University of Maastricht,
The Netherlands;
bhhall@econ.berkeley.edu

Adam B. Jaffe
Brandeis University, USA;
ajaffe@brandeis.edu

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Measuring Science, Technology, and Innovation: A Review

Bronwyn H. Hall[1] and Adam B. Jaffe[2]

[1] *University of California at Berkeley, USA and University of Maastricht, The Netherlands; bhhall@econ.berkeley.edu*
[2] *Brandeis University, USA; ajaffe@brandeis.edu*

ABSTRACT

The measurement of scientific, technological, and innovative activities (STI) in the economy is an increasing challenge faced by statistical agencies around the world. In this review, we survey the current state of the art. We discuss the concept of indicators, their quality and use, and present a schematic model of the STI system that can help us identify gaps in the set of indicators commonly in use. We then review the developments in STI measurement that have taken place in the rest of the world, particularly the widespread use of innovation surveys. The monograph concludes with a discussion of the measurement gaps and issues in the U.S., which we identify as innovation (especially in the service sector), non-R&D investment related to innovation, data timeliness, data linkages, measurement related to public policy goals, and the sources of capital for innovation.

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1

What is an indicator?

An "indicator" is a set of facts or observations that tells us something meaningful about the underlying phenomenon of interest, in this case science, technology and innovation (henceforth STI). In order to evaluate whether a particular set of facts is a good indicator, or to determine whether there are indicators we should have that we do not, we need to consider in some detail what makes a particular set of facts *meaningful*. In this section we address the important dimensions that affect the meaning and usefulness of an indicator.

The foundation of an indicator is a set of data. The word "data" is a plural of the Latin *datum* meaning "given." We frequently think of data in the form of numbers, but conceptually data can be either quantitative or qualitative. Either way, formal analysis of data is predicated on the idea that the data are, indeed, given, meaning that they are generated by the world itself rather than created by the people who want to use them. In reality, what we call "data" in most contexts are numbers or qualitative observations that are usually collected by human beings, and the nature of this collection process combines with the "givens" of the world to determine what are recorded as "data."

For many purposes – particularly their use by policy makers and other "lay" people concerned about science, technology and innovation – presentation of data without further processing does not constitute a meaningful indicator. All of the indicators published by NSF are constructed in some way from underlying data. So any recommendation about an indicator is, in a sense, a compound recommendation: (1) what data should be collected, and (2) how should those data be summarized in a published indicator or indicators?[1]

The relationship between indicators and a framework for analysis of STI

In order to determine whether an indicator is meaningful, we need to assess both the data that are used, and the manner in which those data are summarized. Carrying out this assessment requires specification of the underlying concept we are trying to understand, and the relationship between this concept and the process that generates the data. For example, we tabulate how many academic degrees of various kinds are granted each year. We don't really care about degrees per se, but we care in some way about the knowledge and skills of the population, and we believe that the number of degrees granted and the fields in which they are granted is in some way informative about the accumulation of knowledge and skills. We measure income in various ways. For some purposes, we might care about income itself, but more often we are using income as an indicator of well-being or happiness or success. Sometimes the proxy nature of our measurements is explicit; in other cases it is implicit. But either way, we cannot assess how meaningful an indicator is without thinking about its relationship to the concept or concepts that we really care about.

But where does the statement "the number of degrees granted is in some way informative about the accumulation of knowledge and skill" come from? And why do we think that the population's accumulation of knowledge and skill is itself something we care about? The determination of both what aspects of the real world matter, and what measurements are illuminating with respect to these aspects will be based on some kind of framework, either explicit or implicit. A framework is an abstract representation of the world, typically focusing on one or a small set of aspects (e.g. science, technology and innovation). Such a framework can be constructed and described in a variety of ways: economists like to use symbols and equations; anthropologists tend to use words; systems engineers frequently use diagrams. Whatever the mode of presentation, the framework is designed to capture the essence of the underlying complex reality. Even if such a framework is not fully articulated, it will underlie the choice of data collected and the interpretation placed on the resulting indicators. In this report, we make the framework we are using explicit, because we believe that leads to greater clarity.

---

[1] Data collected by the government are also used in disaggregated form (i.e. without creation of summary indicators) by social scientists and others interested in studying the underlying phenomena. We return below to the importance of the inter-relationship between the collection of data in support of indicators, and the use of data for research.

Having a framework for analysis is also important for the question of how data and indicators can inform public and private decision-making. In order to use data to inform decisions, we again need an understanding of what those data tell us about the workings of the STI system. Either explicitly or implicitly, we have some kind of framework in which those data relate to the instruments or the goals of our decisions. Again, we believe that being explicit about the framework leads to greater clarity in understanding how the data or indicators relate to the goals and instruments of policy.

Note that the relationship between any framework for analysis and data is an iterative one. We need some kind of framework to organize ideas and to know what data we should be looking for, and to support interpretations of the data that we see. At the same time, social scientists and others will use the data to test various models, by studying the extent to which the predictions of their models are borne out in the data. This process may suggest changes to the framework used and also to the data that is needed for analysis. We return below to the implications of this two-way relationship between the data and the model.

In Section 2, we summarize the framework for analysis of the STI system that is most widely used by economists. In this framework, for example, the level of knowledge and skills of the population is important for several reasons: it affects the amount of goods and services that can be produced per capita, and it also affects the rate at which *new* knowledge is produced, which affects the improvement over time in the amount of goods and services that can be produced. In Section 3, we take the next step, and consider how the specific data currently collected by the U.S. government, and indicators constructed from those data, relate to the important concepts within the framework. Section 4 expands this discussion by reviewing data collected and indicators published by other countries and international organizations. Section 5 then turns to the issues of policy, and draws explicit connections between important policy questions and indicators, using the framework of Section 2. Section 6 then builds on these discussions to highlight gaps and issues with the existing indicators. Section 7 provides concluding comments.

Uses of STI indicators

In addition to understanding the data underlying an indicator, how those data were processed, and the relationship of the data and its processing to a framework for analysis of the STI system, evaluating indicators also requires an understanding of the purposes for which they are used.

Performance assessment and benchmarking

Some indicators serve as performance measures that give an assessment of whether the STI system or some component thereof is doing better or worse over time, and better or worse than some comparison group (e.g. other countries). For this purpose, the indicator may stand for some aspect of the system that is intrinsically valued (e.g. income), or it may stand for an aspect of the system that, within the framework, is understood to have important impacts on aspects that are valued. For example, past research has suggested that, all else equal, a greater intensity of investment in new knowledge will lead to higher rates of productivity growth and income growth. For this reason, one might focus on the R&D/GDP ratio over time or across countries as a benchmark of innovative activity. But in doing so, one should always keep in mind the role of knowledge investment in the framework, and the relationship between the framework concept of knowledge investment, and the R&D data that are actually collected. In this example, it is clear that spending on R&D may not capture all of the investments that are directed towards creating new knowledge (and may capture some investment that is not thus directed). In addition, the share of innovation-related investment captured by an R&D measure may be changing over time so that the measure is potentially misleading taken on its own. The framework also makes clear that there is no particular level for this ratio (such as 3%) that is optimal. Finally, even though the relationship between R&D investment and productivity growth is well established, it is still true that R&D investment is an indicator of innovative activity, not an indicator of innovation, which is the concept we think is more closely associated with the growth outcomes of interest.

Informing public policy decisions

An important function of STI indicators is to provide an informed basis for public policy decisions. But of course policy is not intended to affect the indicators, it is intended to affect the underlying concepts of interest. So to determine if a suite of indicators is well-suited to inform public policy, one needs to identify the goals of public policy, and to use the framework for analysis of STI to understand how those goals relate to data that can be collected. We discuss these issues in Section 5.

Informing private sector decision-making

Firms and individuals in the for-profit sector also use STI indicators to make business decisions, and not-for-profit organizations (e.g. universities) use them to make decisions in pursuit of their missions. It is unclear to what extent these parties needs and desires are different from those of policymakers, and, if they do differ significantly, to what extent these distinct needs are considered in the decisions made by government statistical agencies about the STI indicators system.

Facilitating social science research

As noted above, social scientists use data to test the implications of models, and thereby refine the models. Hence their interest in the indicators endeavor is more in the collection and availability of data than in indicators *per se*. But because model testing and validation is so important, we will comment in the concluding section on how the needs of social scientists might be considered in the context of recommendations about indicators.

Issues of data collection and indicator construction

As noted above, though formal statistical theory treats data as "given," in reality the potentially messy process by which the data are created and compiled is sometimes important in evaluating indicators. In this section we identify a few basic issues.

Data dimensions

Data collected to construct indicators may span time, space and institutional categories. Construction of summaries to be reported as indicators can then be aggregated along one or more of these dimensions, depending on the purpose of the indicators. Reporting of indicator values in a time series is frequently of interest; this raises issues of consistency of interpretation of the summary values based on data collected at different points in time. Comparisons across different geographic areas, or across different categories of institutions (e.g. small firms versus large firms), are also of interest. When comparing data from the same point in time, but different institutions or geographic areas, there is an issue of comparability that is analogous to the consistency issue when comparing over time. For analytical purposes, it is often useful to be able to construct a *panel*, in which the indicator of interest varies across both time and another dimension such as geography or institution type.[2] The need for comparability can come into conflict with the need to redesign surveys and data collection methods in response to a changing landscape, especially in the case of indicators describing innovation.

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[2] For micro-data analyses, it is often valuable to have access to longitudinal data, in which data from the same individuals or institutions is collected at multiple points in time.

How the data were generated

Some data collected for use in STI indicators are generated by companies or other organizations in the normal course of their business for their own internal use; some are also generated by these organizations for other external reporting requirements (e.g. financial reporting required by Generally Accepted Accounting Practices). Other data are generated by organizations specifically in response to government requests tied to STI data collection. The advantage of using data otherwise generated in the course of business is that it may be less burdensome for the entities involved. Also, the intrinsic importance of the data elements to the organizations may lead to greater care and consistency in construction, compared to data that are generated only because NSF asks for them. On the other hand, precisely because the data are created for other purposes, they may be less ideally suited to the intended purpose than data that can be specified with their intended STI indicator use in mind.

How the data are collected

For data that are generated for other purposes, there is also a potential distinction between data that are collected by explicit survey requests to the entities that created the data, and data that can be collected passively, i.e. without the active assistance of the generating entities. Examples of passive collection include mining of data from reports filed by companies with agencies such as the SEC or IRS, and “scraping” of data from websites. The advantage of passive collection is minimization of burden on the generating entities. In some cases, there may also be an advantage inherent in the absence of an opportunity for the entities that generate the data to manipulate strategically what is reported. On the other hand, when passively collecting data generated for other purposes, it may be difficult to understand fully what the data really mean and difficult to control the sampling frame to ensure representativenes.

Public versus private data collection

When we speak of indicators, we tend to think of data collected and published by the government. But social science researchers can and do collect data themselves. What is the appropriate mix of government and non-government collection of data and publication of indicators? Data that are of wide potential use have an important public-good attribute. But researchers studying STI can apply for public funding of their research, thus solving the public good aspect of the problem without having the government be the party that collects and publishes the data and indicators. The government does have particular advantages as data collector, where the data in question are related to other data that the government collects for statutory purposes (e.g. census data), and/or the data are considered proprietary and therefore unlikely to be provided by private agents without government mandate. But, by definition, this mandatory data collection principle can only be applied to a limited number of data elements. Recognizing the scope for individual investigators to collect a variety of information beyond what is collected by the government greatly increases the potential scope of indicators available to public and private decision-makers. This is particularly true with respect to data that can be collected passively, as discussed above, because in such a case the requirement of mandatory compliance that the government can bring to its surveys is not necessary. Thus, in considering the possibilities that may be created for additional indicators by passive data collection, we should not assume that these data have to be collected and published by the government. There is considerable scope for individual researchers, probably with public research funding, to collect and publish such data.

Data quality

Before moving on to the framework for analysis of indicators within the STI system, we pause briefly to review measurement issues and how they affect the quality of data. This section draws heavily on Griliches (1986), which can be consulted for more detail.

Griliches categorizes issues of data quality as falling into three categories: extent, reliability and validity. Extent refers to the scale and scope of the data: for how many years has it been collected, how many different data items are collected, and how broad is the coverage in terms of regions or types of institutions. With respect to extent, more is better, in a fairly straightforward way.

Reliability refers to the inherent reproducibility of the data collection process itself. In effect, it asks, if the data were collected on different occasions or in different places, and nothing real about the world were different in the two times or places, how close would the different data be to each other? They won't typically be the same, because each measurement includes random sampling error. Reliability is a measure of the signal-to-noise ratio, i.e., the fraction of the variance in the data that is systematic rather than random.

Validity refers to the extent to which the data are generated and collected in a manner that makes them correspond closely to the underlying concept that we care about. Griliches subdivides validity into considerations of relevance and representativeness. Relevance is, in essence, the question of the extent to which what we are measuring is closely related to what we care about. Representativeness arises in any context in which we collect only a data sample, i.e. we do not collect data from all relevant individuals or units. It refers to the extent to which the different kinds of units had the same probability of contributing to the data (or if the probabilities differed, they did so in a systematic way that we can account for).

To illustrate these concepts, consider the NSF industrial R&D survey. It is very extensive, because it goes back many decades, and covers all firms and all parts of the country. It is reliable, in part because it is so extensive, and in part because the definitions and procedures are well established and understood. But how valid it is really is a question of what underlying STI concept you wish to use it to measure. Its relevance is potentially questionable, because it looks only at formal R&D activities, which may not be the right thing to look at if what we care about is overall knowledge investment. In the past (prior to redesigns in 1992 and 1995) its representativeness may have been questionable, because the sampling frames failed to adequately sample small and medium-sized firms and firms in the service sector.[3] These observations don't mean the data are useless; they simply make the point that the validity of a set of data can only be judged in the context of the framework for analysis of STI and the role to be played by those data within the framework.

As noted above, there is variation in the extent to which the potential gap between the measured item and the model concept is explicitly acknowledged. Virtually everyone who uses patent statistics to measure the rate of invention or innovation notes explicitly that patents are only a "proxy" for the underlying concept. But the issue of proxies is really more one of degree than of kind: for virtually every indicator we use we must acknowledge some degree of potential distance between the measurement and the concept it stands for. Rather than viewing "proxy" as a mild epithet that applies to some indicators but not others, it makes more sense to consider, in all cases, the extent to which a particular indicator might deviate from the underlying concept for which it stands.

It is also worthwhile to consider how the choice of indicators and method of data collection affects their reliability and validity. As noted above, there may be significant benefits in terms of government resources and burden on private parties to expanding the use of data that is passively collected through methods such as web scraping, instead of government surveys. With statistically designed surveys, however, we have both a high degree of reliability, and, perhaps more important, a clear understanding of the level of reliability and possible sources of unreliability. With passive methods, it may be much harder to assess reliability, precisely because the relationship between the captured data and the universe of underlying activity is not known.

Finally, collection of data for indicators has to be sensitive to a variety of different ways in which the collection itself may affect behavior and thereby change the data. The "Hawthorne effect," whereby the mere act of observation may cause people to behave differently, has been understood for some time. In this neutral form, it is not necessarily assumed that one can predict the nature or direction of the change in behavior that results from observation. A more complex and dangerous problem arises from the combination of data that are imperfect proxies for an underlying behavior, with the use of those data to evaluate and reward the people who generate the data.

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[3] See the NSF website for information on the changes in sampling during the 1990s. http://www.nsf.gov/statistics/nsf02312/sectb.htm

For example, it is entirely reasonable to use numbers of published papers and citations as a proxy for the generation of new knowledge. We know that the relationship between the proxy and the underlying phenomenon is imperfect, but as long as the relationship is stable across both time and context, it can be useful indicator. Even if there are differences in the relationship in different times or different contexts, it may still be a useful indicator if we know what those differences are, or can use statistical methods incorporating additional information to correct for them. But if we increase our reliance on such data for the purpose of evaluating and rewarding individuals or organizations, they will then have an incentive to generate more papers *relative to* the rate at which they are generating new knowledge. This can easily generate changes over time in the relationship between the data and the concept of interest, and the extent of these changes may vary across institutional contexts. These effects then make the proxy indicator less informative about the underlying phenomenon of interest.

There is no total solution to this problem, because, as noted above, virtually all indicators are to some degree proxies that may diverge from the underlying concept of interest. But some may be less subject to this kind of endogenous distortion than others. It is also possible that this consideration should weigh in favor of passive data collection rather than surveys, to the extent that people are more likely to respond to the possible incentives created by data collection if they themselves are active participants in its collection.

2

A model of the STI system

In this section we outline a stylized model of the way in which science, technology, and innovation contribute to economic welfare. A science, technology, and innovation (STI) system consists of a number of components linked by the knowledge and resources that flow among them. These components obviously include governments, government research laboratories and extension services, the intellectual property (IP) system, higher education and research institutions, venture capital, and industrial research laboratories. Less obviously, they also include individual actors in any arena that are engaged in improving the efficiency of their production, introducing new ideas and new products, or even making the effort to adopt a new technology or method of organization. When the system works well, the interaction of these institutions and individuals produces welfare-enhancing economic growth via the introduction of new and improved processes, products, and services.

For a comparative study of the operation of different national innovation systems around the world, see Nelson (1993). In that volume, the authors emphasize the importance of interaction among the components of such a system in producing good outcomes. To take a simple example, high quality educational and research institutions are less effective in generating economic growth within a country if firms are not capable of making use of either the graduates or the research output they generate, or these graduates find that employment in secure government research jobs is preferable to working for firms. Another example would be the failure or inability of potential entrepreneurs to put good ideas into practice due to lack of a venture capital system or other form of financing.

The task at hand here is to consider the production of indicators that might help in monitoring such a system and designing policies that enhance its functioning if necessary. Because the innovation system is embedded in the entire economy and touches almost all of it and because it is inherently an intertemporal system, the overall framework used to structure analysis is generally an economic growth model. This model expresses aggregate economic output as a function of ordinary inputs such as capital and labor, and adds to these inputs stocks of intangible knowledge assets, which are assumed to improve the production of output above and beyond the level produced by the other inputs. The use of stocks is intended to capture the idea that knowledge generated in one period is useful in many subsequent periods. These knowledge assets are used to increase the amount of goods and services that can be produced by any given amount of human labor and other inputs. They also may be used to produce desirables such as health, clean environment and national security, which are largely unpriced and may not be adequately included in aggregate output, something we will return to later in our discussion. In addition, to some extent the stock of knowledge may also produce unpriced undesirables. For an example, see Rogoff (2017) on the food manufacturing and marketing industry, where there may have been a negative impact of technical change in that industry on obesity and health, that outweighs the advantages of increased efficiency and lower cost of production.[1]

A stylized version of such a growth model can be written like this:

$$Y \sim C^{\alpha} L^{\beta} K^{\gamma}$$

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[1] A related literature questions the implicit assumption that more innovation is always better. E.g., David (2012) and Soete (2012).

or in growth rate form as:

$$g_Y = \alpha g_C + \beta g_L + \gamma g_K + e$$

In this formulation, Y is output, C is ordinary physical capital, L is labor input, K is a measure of knowledge assets, the gs are the corresponding growth rates, and e is any output growth that cannot be explained by these inputs. In various forms, this model has been used for over 50 years to describe and account for the sources of economic growth (Abramovitz, 1956; Solow, 1957; Jorgenson and Griliches, 1967). However, it is important to note that use of this model requires estimates of the weights α, β, etc. For growth accounting purposes, it is assumed that the capital inputs are supplied competitively. The shares can then be estimated as the nominal shares of nominal income received by the various factors, which creates some difficulties detailed below when knowledge capital is included separately. In contrast, most micro-econometric productivity work estimates the weights α, β rather than computing them from income shares, an approach that requires weaker assumptions on the nature of competition. The result is that growth accounting measures the contribution of the knowledge assets using input costs, whereas the econometric approach measures their contribution using output produced.[2]

Recently the U.S. system of national accounts has begun to incorporate one aspect of knowledge stock, the knowledge produced by R&D investment, both public and private, into a so-called R&D "satellite" account (Carson, 1994). This is feasible because R&D data have been collected over a long time period (from 1953) and therefore stocks can be constructed. Fraumeni and Okubo (2005) use the resulting system of national accounts (specifically the National Income and Product Accounts or NIPA) to estimate the contribution of R&D to economic growth over a forty-year period 1961-2000. They measure the income share of R&D by assuming both a rate of return and a depreciation rate, and perform sensitivity analysis by varying these rates. They found that returns to R&D capital accounted for 7 to 11 percent of real GDP growth, with a range of 4 to 15 percent under their most extreme assumptions. In addition, treating R&D as an investment raises the national savings rate by two percentage points from 19 to 21 percent and has a small positive effect on the measurement of GDP growth because the creation of R&D capital is added to GDP, and R&D has grown faster over time than GDP.

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[2] In practice a number of issues arise due to the lack of firm-level price deflators and the contribution of innovation spending to quality change and market power and therefore pricing. These issues always are there in growth accounting, but become more important when evaluating the role of innovative activity in production, because two of the goals of innovative activity by firms are quality improvement and the creation of market power via product differentiation.

Using the growth accounting framework, indicators can be used to measure both the level of important stocks in this system and the rate of important flows. Both stocks and flows can be measured at different points in time, and the exercise performed at different levels of aggregation, that is, for different kinds of organizations such as business or government, different regions, or different industrial sectors. Possible investment flows that might be considered as indicators include the following:

- The resources that are being expended toward the goal of new knowledge creation, which is largely R&D, but may include other expenditures such as training in new processes or design, engineering and marketing expense associated with new products.
- The resources expended on new capital equipment that is associated with the introduction of new processes and methods of organizing production (broadly defined to include the production of services and nonprofit/government outputs).
- The resources expended in educating scientists and engineers.
- The rate at which advanced degrees in S&E are received.
- The rate at which new knowledge is being generated, such as measures of patents applied for or publications.
- The rate at which knowledge is being transferred between or among different regions or organizations, sometimes measured by citations.

- The rate at which new products or new methods are being incorporated into production of goods and services.

Most of these flows can be transformed into stocks, with varying rates of depreciation, and incorporated into the growth accounting framework described earlier. In section 4 of this report, we describe how the currently available indicators might fit into this system.

Limitations of growth accounting

Growth accounting is a useful schematic for organizing one's thoughts about the sources of economic growth, but it has a number of limitations, especially in the analysis of intangible knowledge and innovation investments. We highlight three: 1) the assumption of normal rates of return; 2) the omission of unpriced output; and 3) that fact it obscures the underlying functioning of the STI system, by focusing only on the input expenditures and the final output in the form of economic growth.

Normal rates of return

The share weights in the growth accounting framework are computed by multiplying an estimate of the annual return to a knowledge asset times a measure of the knowledge stock and dividing by total nominal output. Assuming a stream of investments $R_t, R_{t-1}, \ldots$ and using a declining balance formula with deprecation rate δ to compute the knowledge stock, we have the following equation for the stock:

$$K_t = (1 - \delta_t) K_{t-1} + R_t$$

The share weight for its contribution to growth is the following:

$$\gamma_t = \frac{(r_t + \delta_t) K_t}{p_t Y_t}$$

where pY is nominal output and r_t is the net rate of return to the knowledge investment. These equations depend heavily on the assumed depreciation rate δ that may vary over time, and on the assumption of a normal rate of return. In the absence of markets for knowledge or innovation assets, we have relatively little information on their values and what information we do have suggests that both depreciation and return vary greatly over time (Hall, 2005). In addition, there is the obvious fact that returns to innovation at the industry or economy-wide level, unlike returns to ordinary tangible assets, are not tied down by the discipline of the market, because of the existence of knowledge spillovers.

Unpriced outputs

A second limitation of growth accounting is related to the fundamental question of what we should be measuring as output: GDP or some other concept such as Net Economic Welfare (NEW) or Gross National Happiness (GNH). In the case of innovation, the problem of output measurement centers on the lack of good price data for a set of innovation outputs that include improvements in health from investment in the healthcare sector, national defense, and improvements in environmental quality.

With respect to healthcare, the US Bureau of Economic Analysis is currently engaged in a project to develop a satellite account for health spending that involves the following tasks: 1) creating a set of health expenditure statistics that is common to BEA and the Center for Medicare and Medicaid Services (CMS), and 2) producing a comprehensive set of health care sector accounts for health care income, expenditure, and product.[3] In turn, this involves developing medical care price and real output measures that break out the delivery of health care from increases in the price of that care, rather than simply capture output of the sector via input spending. To the extent that this project is successful, it should improve our ability to track the contribution of spending on health-related innovation to improvements in healthcare.

Popp *et al.* (2010) review the economic research on the impact of innovation in the environmental area, including energy. Much of this research focuses on measurable output, such as pollution levels, or on the inducement of innovative and R&D activity in this area via legislative standards. Another growing area of research is dynamic modeling of the implications of R&D directed at climate change for the economy (e.g., Acemoglu *et al.*, 2012; David *et al.*, 2011). None of this work provides much guidance for translating the intermediate outputs such as reductions in pollution or reduced risk from global warming into measures of economic welfare. But it does suggest that in some areas of innovation, the measurement of direct effects like the reduction in effluents, air and water quality, and so forth, may be relevant.

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[3] For further information about this effort, see http://www.bea.gov/national/health_care_satellite_account.htm (2012).

Evaluating the contribution of innovation to national defense and some kinds of environmental improvement or avoidance of environmental damage is considerably more challenging. This is an area where tracking spending seems the best we can do. In the case of national defense, a long history of analysis in this area points to important spillovers to non-military applications from defense-related R&D investment (Mowery, 2010). Tracking these effects would involve tracking military R&D spending by area, which is already done to some extent. Additional data that might be useful would be entry, growth, and non-military sales shares for firms that contract with the Defense Department to develop new technologies, products, and services. Some evidence of this kinds exists for small firms via evaluation of the SBIR set-asides (Wessner, 2009).

Inside the STI system

The growth model identifies the relevant inputs and outputs, but leaves the mechanisms that connect them unspecified. In the words of Rosenberg (1982), it is a "black box." The inputs are expenditures to increase knowledge stocks and related capital equipment, as well as the quality and education of the labor force. The outputs are knowledge stocks in the subsequent period and output growth. But a number of intermediate inputs and outputs are clearly worth tracking. First, there is the human capital embodied in the labor force, which is partly the creation of the education and job training systems in the economy. Second, the knowledge stocks created by innovation investments are used to produce new and improved products and processes, which in turn lead to the growth of output. Third, the various actors engaged in innovation and knowledge creation interact in ways that add to output and we would like to measure this also, in order to understand the mechanisms that encourage such interaction.

Thus ideally we would like to have indicators for inputs, intermediates, and outputs. To put it another way, we are interested in indicators of innovative activity, innovation, and the impact of innovation on economic welfare. As a general rule, inputs are easier to measure than outputs, mostly because some entity is paying for them so we have a way to aggregate them (using dollar expenditure). On the other hand, the intermediate and final outputs of innovation are often either untraded, or is qualitative, so it is more difficult to measure and to aggregate. That is one reason why we sometimes rely on productivity analysis, which allows the use of national income measures such as GDP, or sales in the case of firms, adjusting these measures for the level of other inputs.

A final observation is that once one goes within the innovation system (unpacks the black box), it quickly becomes clear that there is feedback from later stages to earlier. That is, the so-called "linear model" of innovation is not quite an accurate picture. Various authors, led by Rosenberg (1982), have emphasized this feature of the process.[4] Nevertheless, from a policy perspective, it is natural to think of the model in this way, because it is primarily the inputs (in the form of spending on innovation, basic research, higher education, and the like) that are subject to policy intervention. In addition, it cannot be emphasized enough that innovative output is subject to great deal of uncertainty that is beyond the control of policy or planners. The implication is that although output or success indicators are of interest, they will not turn out to be much of a guide for detailed planning.

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[4] See also Kline and Rosenberg (1986). Balconi *et al.* (2010) present a thoughtful defense of the linear model. Among other things, they point out that in many cases basic science has served as an essential basis for subsequent innovations.

3

Overview of existing U.S. indicators

The state of the existing indicators for the U.S. economy can be seen in the biannual volume published by NSF, entitled Science and Engineering Indicators. Table 3.1 summarizes the indicators available in the latest volume of this publication, dated 2012, and covering data through 2010 in most cases. Although the table suggests an apparent wealth of innovation measures, many of the numbers in it are drawn from administrative records collected for another purpose, and may not be ideal for the measurement of innovative activity. Nevertheless, these statistics provide a very useful starting point. In addition, many of the measures we do have, such as various types of R&D spending and patents granted, are specialized towards the manufacturing sector and technological innovation. Thus they provide valuable, but incomplete coverage of the full range of innovative activities. Other measures, such as value added in various sectors, are bottom line measures influenced by many other factors in addition to innovative activity.

Table 3.1: NSF Innovation Indicators.

Broad area	*Area*	*Indicators available*	*Figure 1 Reference*	*Comment*
Human capital	Elementary and secondary math and science education	Various scores, including PISA; highest skill area;	2 → 4	Quality of human capital creation
		% taught by BA in math or science;	2	Quality of teaching
		% passing APT and % going on to college;	2 → 4	Quality of human capital creation
		Salaries and qualifications of math & science teachers;	1 → 2; 2	Funding of education; quality of teaching
		State standards in math & science	2	Quality of teaching
	Higher education in science and engineering	S&E degrees awarded by type and field;	2 → 4	Magnitude of human capital creation
		Enrollment in higher education by field and nationality;	2 → 4	Magnitude of human capital creation
		Degrees granted by private for-profit institutions;		
		Field of major intentions;	2 → 4	Magnitude of human capital creation
		Sources of support and amount of debt;	2 → 4	Composition of human capital creation
		Foreign enrollment at all levels;	1 → 2; 2	Financing of human capital creation
		Postdocs by field and nationality;	2	Composition of human capital creation
		Spending on tertiary education	2 → 4 1 → 2; 2	Magnitude of human capital creation Financing of human capital creation
	S&E labor force	Occupation of S&E degree holders;	4 → 7; 7	Deployment of human capital in industry
		BLS projections of occupational employment 10 yrs out;	Exp. 4 → 7	Deployment of human capital in industry
		S&E in work-related training;	7 → 4	Human capital creation within industry
		Patenting by S&Es by field and industry sector;	7 → 3	Knowledge creation in industry
		Federal S&E employment;	1; 2	Deployment of human capital in government
		US residents with foreign highest degrees	4	Composition of human capital

Table 3.1: *continued*

Broad area	*Area*	*Indicators available*	*Figure 1 Reference*	*Comment*
R&D spending	R&D spending	US R&D spending by sector, source of funds, state;	1 → 2, 5, 7; 7 → 5,6	Funding of knowledge creation
		Basic, applied, and dev. R&D by sector, source of funds;	ditto	Composition of knowledge creation
		Federal R&D budget authority or obligations by function & character of work, agency, location;	1 → 2, 5, 7	Federal funding of knowledge creation
		Federal R&E tax credit claims by NAICS;		
		R&D spending by foreign affiliates in US by NAICS & country;	1 → 7	Federal subsidy of industry research
		R&D spending abroad by US firms by NAICS & region;	7	Source of industry funding of knowledge creation
		Contract R&D in US by NAICS;	7	Location of industry-funded knowledge creation
		US trade in R&D and testing services;	7	Composition of industry funding of knowledge creation
		Tech alliances by type, technology, country	7	Location of industry-funded knowledge creation
		SBIR and STTR awards by type & agency;	5; 7	Nature of partnerships
		ATP projects, TIP, Mfg extension information	1 → 7	Federal funding of industry knowledge creations

Table 3.1: *continued*

Broad area	*Area*	*Indicators available*	*Figure 1 Reference*	*Comment*
R&D spending	Academic R&D	Academic R&D for basic, applied, development;	2 → 3	Composition of knowledge creation
		Support for academic R&D by sector;	1 → 2; 7 → 6	Funding of academic knowledge creation
		Federal support to acad. R&D by agency & character of work, field;	1 → 2; 1 → 5	Federal funding of academic knowledge creation
		Academic R&D by field and source;	1 → 2; 7 → 6	Funding of academic knowledge creation
		Faculty in S&E by field;	2	Composition of academic sector
		S&E doctorates in academia by field, type of work, nationality, type of support, collaboration	2 → 4	Magnitude of university human capital formation
		S&E publication data by field and region;	2 → 4; 7 → 4	Knowledge creation
		Internationally co-authored pubs by selected country pairs;	2 → 4; 7 → 4	International composition of knowledge formation
		US utility patent awards by owner type;	7 → 3; 2 → 3	Knowledge creation
		Academic patent licensing;	2 → 3 → 7	Academic-source knowledge used in industry
		Citations of papers in US patents by sector and field	3 → 7	Use of knowledge in industry

Table 3.1: *continued*

Broad area	*Area*	*Indicators available*	*Figure 1 Reference*	*Comment*
Commercialization	Industry, technology & globalization	VA of K-intensive, ICT, high-tech & other industries by country;	7 → 8	Commercialization of technology
		VA of education, health, business, financial services by country;		
		Exports & imports of high-tech goods by country and broad sector;	7 → 8	Commercialization of technology
		US trade in high-tech goods by country and sector;	7 → 8	Commercialization of technology
		Domestic & foreign VA and employment by US MNEs by sector;	7 → 8	International spillovers
		US FDI abroad and foreign FDI in US, by industry	3	International spillovers
		US receipts & royalty payments from foreign affiliates;	7 → 3	Knowledge creation by industry
		US patent apps and grants by country, technology;	7 → 8	Innovation
		US trademark apps and grants by country, technology;	7 → 3	Knowledge creation by industry
		Triadic patent families by country;	9 → 7	
		US VC investment information		

Table 3.1: *continued*

Broad area	*Area*	*Indicators available*	*Figure 1 Reference*	*Comment*
Attitudes	Public attitudes to S&E	Primary sources of information about news & science;	n.a	Environment for innovation
		Public interest in selected issues;	n.a	
		Visits to science & cultural institutions;	n.a	
		Correct answers to various science questions;	n.a	
		Assessment of govt spending on R&D and quality of science education in US;	n.a	
		Attitudes towards nanotechnology, stem cell, animal research, by country;	n.a	
Regional	State-level information	Average math & science scores;	2 → 4	Quality of human capital formation
		S&E doctorate holders, employed and otherwise;	4	Human capital stock
		See above for R&D information		

Source: US NSF STI Indicators (2010) with authors' additions to columns 4 and 5.

Figure 3.1 presents a schematic summary of how resource inputs, knowledge outputs, and ultimate impacts flow in the economy, providing a framework for assessing which aspects of the system are captured well by existing indicators and which are captured less well. The blue rectangles represent the main actors in the knowledge economy-government, the education sector including public research organizations, various industries, and the finance sector. The red hexagrams represent the two main classes of research and innovation collaboration, between industry and university, and between public (governmental) and private organizations. The yellow ovals are the two intangible assets of the knowledge economy, which are difficult to measure: the knowledge base (largely codified and/or not embodied in individuals) and human capital (largely tacit and/or embodied in individuals). The green arrows represent flows of resources (funding) from one sector to another, and the dotted arrows represent intermediate knowledge outputs that flow between and among the sectors. The heavy dark arrow at the bottom indicates that the for-profit sector, using both internally and externally generated knowledge, generates commercial innovation, which is then manifested in output growth, productivity improvement, and enhancement of individual welfare.

The Figure is designed to capture, in a stylized way, the important investment mechanisms and the important impact pathways of the endogenous growth model described in the previous section. We see, for example, that both the education sector and the industry sector contribute to the creation of new knowledge and new human capital, and these knowledge stocks in turn feed back into both the education and industry sectors to foster cumulative knowledge growth. Within the industry sector, we have shown two (of many) industries, to represent that knowledge spillovers flow between industries, as well as between firms in a given industry (illustrated within the right-hand industry in the diagram). Also within industries lie R&D labs, which are largely funded from within industry, but also receive public funds. These labs are a source (but not the only source) of knowledge creation within the industrial sectors. Finally, the government is a major funder of all of the knowledge creation sectors.

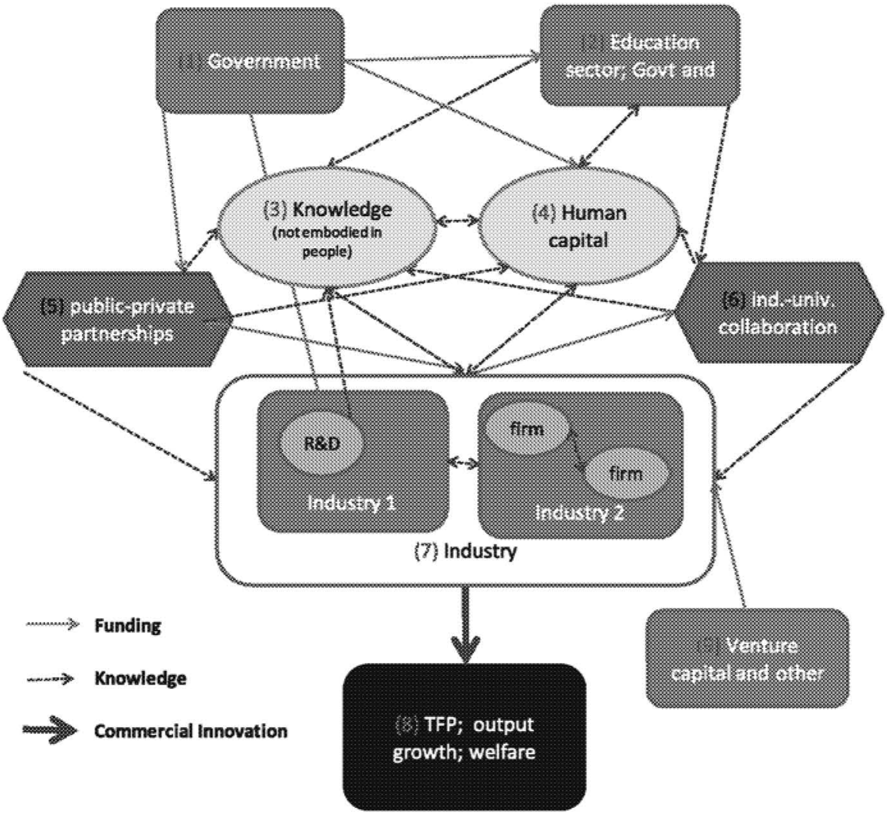
Government
Education sector; Govt and
(3) Knowledge (not embodied in people)
(4) Human capital
(5) public-private partnerships
(6) ind.-univ. collaboration
R&D
Industry 1
firm
firm
Industry 2
(7) Industry
Funding
Knowledge
Commercial Innovation
TFP; output growth; welfare
Venture capital and other

Figure 3.1: Schematic Overview of the STI System.

The last two columns of Table 3.1 show the connections between the STI Indicators currently published by NSF and the stocks and flows in Figure 3.1, using the numbers that appear in each polygon in Figure 3.1 to make the connections So, for example, in the first row of the table, an indicator related to elementary and secondary test scores is labeled " 2 → 4," indicating that it corresponds to the arrow connecting the rectangle (2) to the oval (4) in Figure 3.1.

Perusal of Table 3.1 and Figure 3.1 together indicates that our existing indicators are quite complete in their coverage of the resource flows that support the generation of new knowledge, containing considerable information about the magnitude and distribution of those flows. There are also multiple indicators that correspond to knowledge and human capital outputs, although these measures are universally proxies that are related to the underlying concepts with substantial measurement error (e.g., degrees as a measure for the human capital of graduates; papers as a measure of new scientific knowledge; patents as a measure of new technical knowledge). The measures of innovation (as opposed to innovative activities) are much less complete, and arguably more "distant" from the underlying concepts. For example, the errors of both over-inclusion and under-inclusion in using new trademark registrations as a proxy for innovation are probably even greater than the corresponding errors in using patents as a proxy for new inventions. And a similar observation applies to using high-tech value added as an indicator for increased output that can be attributed to innovation.

We will return to a discussion of the potential issues and gaps in the existing NSF Indicators, after a discussion in the next section of analogous data collection and publication efforts in other countries.

4

International context

Almost every developed and mid-level developing country in the world has been concerned to some extent with the problem of measuring innovation. Broadly speaking, most have arrived at some combination of R&D spending, tertiary education, patenting activities, publication activities, research funding availability, and success in exporting and growth. In addition, many countries have made use of the innovation surveys pioneered in Europe to assess the innovative activities of their own firms. See Table 4.1 for a list of the countries that have fielded one or more innovation surveys.

Two aspects of these international efforts are important for the U.S. innovation indicator enterprise. First, as a latecomer in some areas of measurement, we can learn from the experience of others. Second, the fact that many countries are constructing "innovation scoreboards" means that there is a demand for international comparability of at least some of these measures, in order to facilitate various kinds of benchmarking. However, exact comparability is difficult to achieve due to differences in the ways questions are interpreted, the structure of industrial firms, and differences in the cultural and institutional contexts.

Table 4.1: Innovation Surveys.

Region	*Countries*	*Website*
EU27	Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg Malta, Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden, UK	http://www.proinno-europe.eu/metrics
Rest of Europe	Norway, Switzerland	http://www.ssb.no/innov_en/ http://www.kof.ethz.ch/en/surveys/structural-surveys/
Latin America	Argentina, Brazil, Chile, Colombia, Cuba, Ecuador, Mexico, Panama, Peru, Trinidad and Tobago, Uruguay	http://www.ricyt.org
Asia	Japan, Korea, Malaysia	http://www.nistep.go.jp/en http://www.kistep.re.kr/en/c3/sub2.jsp
Pacific	Australia, New Zealand	
Other	Canada, South Africa	http://www.statcan.gc.ca/concepts/index-eng.htm

Both DIW and NESTA (discussed below) have introduced several measures that might be used to capture some of the cultural differences across countries. These measures include some that are already collected by the NSF, such as attitudes to the development of technology despite its potential risks, and evidence on the public's interest in new inventions and technologies. Additional measures that might be useful are those for buyer sophistication with respect to innovation, the level of computer and internet skills, social capital and trust. A particularly salient measure for the development of entrepreneurship is the measure of the fear of failure, which is frequently identified as an important reason for lower entrepreneurship rates in Europe, but might also be useful for comparing regions within the United States.

Table 4.2 below gives an idea of the innovation indicators that are being measured by the European Union. Some of them reflect particularities of the European institutional setting. A couple of examples: 1) The focus on measuring climate change mitigation innovation is due to a strong policy stance of the EU with respect to green technology.[1] 2) The age restriction on doctoral graduates is probably because it is extremely unusual in Europe for anyone to go back to school for a doctoral degree at older ages, unlike the situation in the U.S. However, in general similar indicators can be or already have been constructed for the United States, with the notable exception of those based on the innovation survey questions, at least to date. In the following subsection we discuss what has been learned from others' experience with these surveys, and what the U.S. is doing in this area.

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[1] E.g., see the Europe 2020 agenda for growth. http://ec.europa.eu/europe2020/index_en.htm

Table 4.2: European Union Innovation Indicators.

Input or output	*Broad area*	*Indicator*	*Available in US?*
Input indicators (human capital)	Human capital	New doctorate grads per 1000 pop aged 25-34	New PhDs
		Share of pop aged 30-34 having completed tertiary educations	Yes
		Share of youth aged 20-24 having attained at least upper secondary level education	Yes?
	Research system	Intl. scientific co-publications per million pop.	In principle
		Scientific publications among the top 10% most cited publications worldwide as % of total scientific publications of the country	In principle
		Non-EU doctorate students per million pop.	Non-US
Input indicators (industry)	Finance	Public R&D spending as share of GDP	Yes
		VC (early stage, expansion and replacement) as share of GDP	?
	Firm investment	Business R&D spending as a share of GDP	Yes
		Non-R&D innovation spending as a share of turnover	No
	Linages and Entrepreneurship	SMEs innovating in-house as a share of SMEs	Not at present
		Innovative SMEs collaborating with others as a share of SMEs	No
		Public-private co-publications per million pop.	In principle

Table 4.2: *continued*

Input or output	*Broad area*	*Indicator*	*Available in US?*
Intermediate output indicators	Knowledge assets	PCT patent applications per billion GDP	Yes
		PCT patent applications related to societal challenges per billion GDP (climate change mitigation; health)	In principle
		Community trademarks per billion GDP	US trademarks
		Community designs per billion GDP	US trademarks
Output indicators	Innovators	SMEs (>10 employees) introducing product or process innovations as share of SMEs	Not at present
		SMEs (>10 employees) introducing marketing or organizational innovations as share of SMEs	Not at present
		High-growth enterprises as share of all enterprises (???)	??
	Economic effects	Employment in knowledge-intensive activities (manufacturing & services) as a share of total employment	Yes
		Medium and high-tech manufacturing exports as a share of total product exports	Yes
		Knowledge-intensive services exports as a share of total service exports	possibly
		Sales of new to market and new to firm innovations as a share of turnover	Not at present
		License and patent revenues from abroad as a share of GDP	Yes

Source: European Union (2012, 2012) and authors additions.

Innovation surveys

The challenge of measuring innovation broadly has been met at least partially during the past 20 or so years by the introduction of direct surveys of business firms in many countries. Although earlier pioneering surveys of various kinds exist, this activity really took off with the publication of the first edition of the Oslo Manual in 1992 (third edition, Tanaka *et al.*, 2005), which had guidelines for the definition of various kinds of innovation and for the collection of innovation-related data. For example, several non-R&D kinds of innovative expenditure were identified in the manual: the later phases of development and testing that are not included in R&D, capital expenditures related to the introduction of new processes, marketing expenditures related to new products, certain kinds of employee training, expenditures on design and technical specifications, etc.

The Oslo Manual defines innovation as follows:

> "An innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations."[2]

In spite of the apparent clarity of this definition, measuring innovation in a form that is useful for statistical analysis has proved challenging. The central problem is that no two innovations are alike. Some innovations (e. g., the invention of the telephone or perhaps the telegraph) create a whole new market sector whereas others are useful but trivial, and there is a wide range in between. In general we can say that smaller innovations are more numerous than game-changing ones. As an illustration of this phenomenon, consider the data of Acs and Audretsch (1990), who collected a comprehensive list of innovations introduced by business firms during the year 1982. Over 85 per cent of the innovations they identified were modest improvements to existing products, and none created entire new markets. Fewer than 2 per cent were considered even the first of its type on the market in existing market categories.[3]

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[2] *Oslo Manual* (Tanaka *et al.*, 2005), third edition, p. 46.

The NSF has recently redesigned the industrial R&D survey and renamed it the Business R&D and Innovation Survey (US-NSF, 2009). In doing the redesign, they added a pilot question on innovation similar to those in the European CIS (Community Innovation Survey) in 2008:

> Did your company introduce any of the following during the three-year period, 2006 to 2008?
>
> 1. New or significantly improved goods (excluding the simple resale of new goods purchased from others and changes of a solely aesthetic nature).
> 2. New or significantly improved services.
> 3. New or significantly improved methods of manufacturing or producing goods or services.
> 4. New or significantly improved logistics, delivery, or distribution methods for your inputs, goods, or services.
> 5. New or significantly improved support activities for your processes, such as maintenance systems or operations for purchasing, accounting, or computing.

Unfortunately, for a number of reasons, including survey design, coverage, and nonresponse, the results from the pilot question cannot really be compared with those from other countries (Hall, 2011; Jankowski, 2012). In response to the problems they encountered with this first trial, the NSF redesigned the survey in the following year, moving the innovation question to the front of the survey and adding several other questions, but the data for 2009 and 2010 have not yet been released so that we are unable to use them in this report. Preliminary numbers in Jankowski (forthcoming, 2013) suggest that the U.S. innovation rates are still substantially lower than those for European countries, but issues of firm size and sector coverage comparability still remain.

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[3] Note that by using the 1982 date, Acs and Audretsch did miss two major innovations: the IBM personal computer and Microsoft DOS, both of which were introduced in 1981 and which arguably meet the definition of "created entire new market".

The innovation data produced by the European CIS have been widely used by economists in models of R&D, innovation, and productivity, so we have learned something about their quality (Mairesse and Mohnen, 2010). The main variables used have been the binary indicators for product and process innovation at the firm level. Although they are clearly related to the conduct of R&D in the data (especially in the manufacturing sector), they are also very noisy indicators of the underlying innovation concept.[4] Given a choice between the amount of R&D spending, or a binary innovation indicator to predict productivity growth at the firm level, the estimation models clearly prefer R&D spending as an explanatory variable, when it is available. However, since many innovating firms do not report that they do any R&D, the innovation indicator can still be useful.

A simple thought experiment will demonstrate why a binary innovation indicator has limitations: imagine comparing the answers given by a micro enterprise and a large multinational to the question of whether they have introduced a new product or process during the past three years. Clearly, if the large multinational answered no, we would be worried about its survival, whereas it might be perfectly normal for a small enterprise to innovate, but possibly not at less than three year intervals. But have we learned that the small enterprise is less innovative than the very large one? Not necessarily. In contrast, R&D is a continuous variable that can be transformed into the intensity with which a firm invests in technological innovation.

Alternatively, consider comparing two larger enterprises, both of which introduce a new product, but one of them captures the market, and the second enters a market new to it and fails to get more than small share, while remaining profitable due to its old products. Both will be recorded as innovative, but the result is clearly quite different. The amount they earn from innovation as a share of sales would be a lot more informative. In the case of product innovation, fortunately the share of sales due to new products has been collected by the CIS (and will be collected in future U.S. surveys) and this has turned out to be a better predictor of productivity than the simple binary variable, especially in the absence of a measure of spending on innovation. It would be desirable to try to collect a similar measure for process innovation.[5] If one cannot obtain estimated cost reduction from this kind of innovation, it might be possible to use measures of investments in new capital and training that are associated with the introduction of new processes.

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[4] Hall *et al.* (2013) report that in the UK, the share of service sector innovating firms that do not do any type of R&D (including external, capital equipment for new process, and training) is about twice that in the manufacturing sector.

All this suggests a couple of ways that innovation surveys could be improved to capture a full picture of firm innovative activity. Some of these have already been discussed in the Oslo Manual, but have not been incorporated into most innovation surveys. The first would be a focus on trying to measure the benefits of process or organizational innovation in a more quantitative way. For this purpose, the Oslo Manual suggests first asking whether the innovation led to a reduction in cost, and then asking by how much:

> "These questions can either be asked with respect to average costs or to specific costs, for example changes in the cost of material, energy or labour inputs. Quantitative questions can either ask for an interval estimate of the percentage change in costs, or ask enterprises to choose from a set of predefined categories (e.g. an increase or decrease of less than 5%, 5% to 25%, over 25%). Experience from earlier surveys indicates that enterprises find the latter method easier to answer and thus results in much higher item response rates. The same techniques can also be used to ask about the effect of process innovations on employment, i.e. whether employment increased or decreased, and by how much." (Oslo Manual, third edition, page 111).

A second area where more information than currently available would be helpful is expansion of the information collected on innovation expenditures (question 5.2 on the standard CIS questionnaire). Currently some but not all of the innovation surveys in Europe collect information on the following categories of expenditure:

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[5] Peters (2006) reports on such an effort in Germany.

- In-house R&D - including software development in-house
- External R&D - performed by other enterprises (including other enterprises or subsidiaries within your group) or by public or private research organisations and purchased by your enterprise
- Acquisition of machinery, equipment and software used to produce new or significantly improved products and processes
- Acquisition of external knowledge - Purchase or licensing of patents and non-patented inventions, know-how, and other types of knowledge from other enterprises or organisations for the development of new or significantly improved products and processes
- Training for innovative activities - Internal or external training specifically for the development and/or introduction of new or significantly improved products and processes
- Market introduction of innovations, including market research and launch advertising
- Design - to improve or change the shape or appearance of new or significantly improved goods or services
- Other - Other activities to implement new or significantly improved products and processes such as feasibility studies, testing, routine software development, tooling up, industrial engineering, etc.

In some cases only a yes/no answer is required for the above in the current surveys, but the data would be considerably more useful if actual expenditure data can be collected.

A final suggestion for additional data that might help correct the bias introduced by sectoral variation in the meaning of a new product also comes from the Oslo Manual:

> “In order to take into account the effects of product life on this indicator [the introduction of a new good or service in the past three years], it is suggested that the firm should be asked to give an estimate of the average length of its products’ life cycles. This information could be used to weight the percentage shares suggested above. An alternative way of putting this question is to ask how often the firm usually introduces innovations.” (Oslo Manual, third edition, page 110).

We have not found any evidence that this question has ever been attempted in an actual innovation survey, so it is hard to evaluate whether the answers would be helpful. However it does see worth considering as an indicator that would help interpretation of the innovation indicators themselves.

Other innovation indicator efforts

In this section we catalogue a few other efforts toward constructing innovation indicators, by the World Bank, the UK government, and a research institute in Germany, the Deutsche Institut für Wirtschaftsforschung (DIW).

World Bank

KAM is the Knowledge Assessment Methodology developed by the World Bank, which consists of 4 pillars:[6]

- Economic Incentive and Institutional Regime
- Education
- Innovation
- Information and Communications Technologies

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[6] http://www.worldbank.org/kam

From these pillars, each of which contains a number of individual measures, they produce two indices: a Knowledge Index (KI) and a Knowledge Economy Index (KEI). The Knowledge Index is based on education, innovation and ICT investment. The Knowledge Economy Index adds the economic incentive and institutional regime pillar to this.

As is clear from the website, these measures are primarily input and institutional measures, describing the framework in which the knowledge economy can grow, and intended as a diagnostic and benchmarking tool for the World Bank client countries. The website provides a range of different "scorecards," including custom combinations of indicators, that can be consulted by policymakers.

UK NESTA (for the UK Dept of Business, Innovation, and Skills)

A study of wider frameworks for innovation (Allman *et al.*, 2011). This study focuses to some extent on indicators that are designed to measure UK underperformance in innovation environment such as fear of failure, entrepreneurial activity, ICT take-up, etc. They divide indicators into five categories and produce a long list of indicators for each one:

- Public research base and linkage to industry
- Demand conditions and competition
- Supply of high quality human resources and finance
- Infrastructure and services in the economy
- Degree of entrepreneurship

Among the detailed lists that they give, these indicators are already present in most collections:

- Gross Expenditure on Research and Development
- Share of GBAORD as per cent of total general government expenditure

- Higher Education R&D as percentage of GDP
- Percentage of BERD financed by abroad
- Percentage of BERD financed by the government
- Percentage of HERD financed by the private sector
- Publications per 100,000 population
- Publications per million dollars
- Average annual citations per HERD Expenditure
- Patents, Invention Disclosures and Licenses
- Sources of Universities Research Income
- Firms with new-to-market product innovations by size
- Patents and trademarks per capita, 2005-07
- Number of scientific & technical articles cited in patents
- Citations to academic patents
- Market Capitalisation of listed companies (percentage of GDP)
- Venture capital investment as a percentage of GDP by early stage and expansion
- Share of employment in KIBS, 2009 54
- Education expenditure and performance
- Human resources in science and technology as a share of labour force (%)
- Costs of firm entry

The indicators below are potentially new. We have grouped them according to the areas about which they provide information.

End-user demand for innovation (consumers):

- Interest in new inventions and technologies
- Consumer Confidence Index
- Buyer sophistication: ability of buyers to understand innovation and use it
- Final consumption expenditure of households: communication share

End-user demand for innovation (firms):

- Government procurement of advanced technology products
- Value of public procurement which is openly advertised as a % of GDP
- Firm-level technology absorption
- Cooperation with clients
- Intensity of local competition

Startups and firm growth:

- Births, Deaths and Active Stock indicator
- Employer enterprise birth and death rates
- Fear of failure rate
- Early-stage entrepreneurial activity distinguishing necessity and opportunity
- High-growth early stage entrepreneurial activity
- Global market penetration by SMEs
- Cost of access to IPR services

Financing:

- Ease of access to loans
- Venture capital availability
- Ease of access to local equity markets

Labor markets:

- Employment in creative sectors as a share of employment
- Individuals' level of computer and internet skills
- Life-long learning
- Workforce development indicators (firm-level OJT, etc.)
- Choice, discretion and creativity at work (survey)
- Share of firms with co-operation agreements with government or higher education

Diffusion of new technologies

- Business use of mobile internet
- 3G (and higher) coverage
- 3G or higher cellular mobile adoption
- e-Intensity Index (Boston Consulting Group – weighted sum of a nation's supply of Internet infrastructure and the demand for Internet services)
- Business use of social networking

The above lists are very comprehensive and it is not at all clear that it is even feasible to collect many of the measures, or that all of them would add information to what we already know. However, some of them have the potential to be useful, especially those focused on demand side considerations and diffusion, neither of which are especially well-measured in our current set of indicators.

Deutsche Institut für Wirtschaftsforschung (DIW)

Belitz *et al.* (2011) describe an effort by the DIW in which they computed a composite indicator for 13 EU countries, Japan, Korea, the US, and Canada and do some sensitivity analysis. Unfortunately they are not very specific about which measures they use and how exactly the variables are measured. The subindicator components are the following:

- Education
  - Costs
  - Output in terms of grads
  - PISA scores
  - Lifelong learning
- R&D
  - Spending
  - Patents
  - Publications & citations
- Financing
  - General financing conditions
  - Financing of startups
  - Public R&D support
  - Tax policy
- Demand
  - GDP per capita
  - Domestic demand for innovative products
  - Measures of buyer's sophistication, firm level technology absorption and government procurement of advanced technology products

- Networking
  - degree of inter-company networking
  - alliances with suppliers and customers
  - R&D cooperation, esp. internationally
- Implementation
  - Research intensive VA and employment, balance of payments
  - Valuations of Transport and Energy systems, Network Readiness and E-Readiness
- Competition
  - Product Market Regulation (PMR) index of the OECD
  - Measures of competition and corruption fighting
- Societal innovation climate
  - World Value Survey Data for openness to new technologies and formation of social capital
  - Eurobarometer Data for trust measures and concerns about science and technology.

5

STI indicators for STI policy

As noted above, indicators are desired to some extent merely for the purpose of a scorecard or benchmarking of the level of activity in different areas. And it is important for the advance of social science that the data underlying STI indicators be available. But consistent with the idea of "The Science of Science and Innovation Policy," it is also desirable for the indicators to be as helpful as possible in informing major public policy decisions. In this section, we survey briefly how indicators can (and often cannot) meaningfully inform policy choices.

Overall level of public investment in R&D. Implicitly, the Congress and the President are continuously deciding what overall level of resources to invest in new knowledge creation through the R&D process. Ideally, this would be informed by data showing the marginal rate of return on these investments. But marginal rates of return are very difficult to measure. Economists and others have made estimates of the average rate of return to R&D investments (Hall *et al.*, 2010). Within the model, the marginal rate of return declines with the intensity of R&D investment (R&D/GDP) other things equal, so a high average rate of return is a necessary but not sufficient condition to justify increased investment.

In the absence of explicit information, R&D intensity measures do provide some implicit evidence on the rate of return. Economic models typically presume that there are diminishing returns to increased R&D expenditure, so that the rate of return to R&D will fall as R&D/GDP rises. This means that if today's U.S. R&D/GDP ratio is lower than at another point in time, we may be able to infer that the rate of return in the U.S. today is higher than it was at that point of time, assuming that nothing else has changed. The same argument applies when comparing R&D intensities across countries, although it is even more difficult to assume that other things are equal in that case. Thus if we have some reason to believe that the investment level was right at some point in time, then we might be able to infer that the implied high rate of return in the U.S. today justifies a higher level of investment (and vice versa if today's U.S R&D intensity is higher than at some other time or place). However, given all the uncertainties, it would probably be better to attempt to measure the return to R&D spending in this case.

Overall level of public investment in education and training. The issues with respect to the optimal level of investment in education and training are analogous to those related to R&D. We would, ideally, like to have measures of the rate of return; measures of the current ratio of investment to GDP may provide indirect evidence on the rate of return, at least relative to other times or places. In addition, public policy may view having an educated public as a desirable end in itself, over and above any return it may provide in terms of innovation and technology. If so, then data on years of schooling and degrees awarded are useful policy indicators independent of their indirect implications for the economic rate of return.

Education and training also take many forms and occur in many different contexts. We have better data on what occurs in formal educational institutions than we have on training that occurs on the job, or is otherwise provided by firms without recourse to formal educational institutions.

Allocation of both of above by scientific/technical area or area of ultimate application. Even more than the overall determination of public investment, the government must continuously decide the allocation of public resources for R&D and education/training across scientific and technical fields, and across areas of application. Again, within the model the most relevant information for these decisions would be the marginal rates of return. And again, these are hard to measure, and measurements of average rates of return are incomplete as indicators of marginal rates. In addition, there are substantial spillovers across scientific fields (e.g., the importance of computer science for DNA analysis) so that localized rates of return may not capture the true importance of some fields.

The relevance of investment intensity measures as indirect indications of marginal rates of return is more complex in the context of allocation across fields or sectors. If the inherent technological opportunity is greater in a given sector, then its marginal returns are higher at any given level of investment. Thus it is possible, for example, that our much higher level of public investment in research in health sciences than in other fields represents an implicit belief that technological opportunity, and hence marginal returns, are higher in that area than in others. On the other hand, no other country in the world devotes such a large share of its public research investment to health sciences. Unless the variation of technological opportunity across fields is different in different countries, comparative benchmarking on sectoral allocations may provide indirect evidence on rates of return. As noted above, however, this is a particularly problematic sector due to the difficulty of measuring output properly and the fact that health improvements are not completely capture by national income accounts.

Allocation of federal R&D and training resources by types of institutions (e.g. intramural versus extramural or universities versus firms). Allocation of public resources across different kinds of institutions raises the same issue of relative rates of return as allocation across sectors. In addition, different kinds of institutions play different roles in the STI system. Hence indicators reflecting intermediate outputs of the research process, and flows of knowledge within the system, might be informative about imbalances within the system. It would also be useful to construct and publicize more detailed statistics on the demand for S&T skills in certain areas, including starting salaries, in a timely manner.

Science and technology policy choices other than spending. Many government policy choices explicitly or implicitly affect the STI system, including R&D subsidies (and other tax policies), intellectual property rules, and mechanisms for the transmittal of funds (e.g. basic research grants, contract research, prizes, etc.). It is not clear that indicators, as we normally think of them, shed light on the relative efficacy of different policy choices of this kind. But the data collected as the basis for indicators can also be used by social scientists to study the relative effectiveness of different mechanisms. In fact, these data are essential for this purpose.

Immigration policy (as applied to scientific/technical workers). Indicators related to the number of number of scientific and technical workers, combined with the level of investment in research, may be useful for informing the nature and extent of visa programs to allow more technically trained immigrants to work in the U.S.

Indicators for use by university administrators or firm managers? Firm managers and university administrators face many of the same choices as governments: how much to spend and what to spend it on. Many of them rely to some extent on benchmarking, that is, observing the spending patterns of their immediate competitors. Therefore the same kinds of data as described above can be useful, preferably broken down by sector and by geography.

6

Issues and Gaps in existing U. S. indicators

In this section we identify a few broad areas where consideration of the STI framework relative to the existing indicators, and learning from data collection efforts in other countries, suggest areas for possible expansion and improvement of U.S. indicators. In the Concluding Section, we move to a broader examination of STI indicators relative to the Key Issues and Questions identified by the Panel in their Interim Report.

Innovation measures

As discussed above, the Europeans have pioneered the collection of data on innovation through the implementation of the Oslo manual. The new BRDIS surveys already administered for 2009 and 2010 should give us more information on this activity. Unlike the 2008 survey, these surveys began with a page of questions about innovative activity, including the following:

1. Whether the firm introduced
    (a) new or significantly improved goods
    (b) new or significantly improved services

   (c) new or significantly improved methods of production
   (d) new or significantly improved logistics, delivery, or distribution methods
   (e) new or significantly improved support activities
2. Was any of the above new to the market or only new to the firm.[1]
3. Give percentages of sales due to 1) goods & services new to the market; 2) good & services new to the firm only; 3) goods & services that are not new. Must add to 100%.

As discussed above, existing analyses of data from the European surveys suggests that yes/no answers to the innovation question in (1) create very coarse indicators that provide very weak measurements of the impact of innovation on such things as productivity. Question 3 is more promising in this regard, but it provides quantitative impact data only for the innovations corresponding to questions 1a and 1b. This survey will not collect any information about the cost-savings and employment changes from the kinds of innovations covered by 1c, 1d, & 1e. Given the importance of these innovative activities in service-related sectors and non-R&D innovation, future work might want to explore improving the measurement of the benefits of process and organizational innovation. As discussed below, it would also be very useful to add a version of question 5.2 from the CIS (non-R&D expenditures on innovative activities) to the BRDIS survey.

Innovation in the service sector

There is no doubt that the service sector (broadly defined) is an increasingly important part of most developed economies: in the U.S., sectors producing services now account for 69% of private non-agricultural employment and 69% of value added in GDP as compared to 9% and 17%

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[1] The way this question is posed might have been confusing if the firm answered yes to more than one item in (1).

respectively for the goods-producing sectors including manufacturing.[2] However, historically US data collection efforts related to innovative activity have focused on manufacturing, even though the service sector has been more important in economic terms than manufacturing for some time.[3] To some extent, the focus on manufacturing reflects a traditional science and technology view of innovative activity, one that centers on organized R&D laboratories and research employees. In the service sector, much of the effort at knowledge creation and innovation does not occur in organized research labs, and is undertaken by employees who are not categorized as researchers, making it harder to measure innovation effort.[4]

As services have become more important to the economy, and their innovative activity more obvious, it has become clear that more effort needs to be focused on data collection in services, where spending on R&D is a less useful measure of innovative investment. One can get a rough idea of the importance of innovation in the service sector from the results of the CIS surveys in the European Union.[5] In 2005, 39% of firms in the manufacturing sector reported that they had introduced either a product or process innovation (or both). For the service sector as a whole, the number was 34%, whereas for knowledge-intensive business sectors (KIBS) it was 52%.[6] These numbers clearly suggest the importance of capturing this activity by broadening of data collection efforts. One could argue that these numbers would be even higher in the United States, which has been a leader in ICT-related process reorganization and in the production of information services.

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[2] *Economic Report of the President* (2011), Tables B-12 and B-46. The service-producing sectors includes utilities, wholesale trade, retail trade, transportation and warehousing, information, finance, insurance, real estate, rental, and leasing, professional and business services, educational services, health care, and social assistance, arts, entertainment, recreation, accommodation, and food services, and other services, except government.

[3] E.g., see the historical NSF statistics on R&D spending by sector, which reflect the bias toward manufacturing in the sampling frame during earlier years. In 1992, the non-manufacturing sector was reported as responsible for 25 per cent of R&D spending, whereas in 1980, only 4 per cent. These numbers are unlikely to accurate reflect the actual increase in spending among the non-manufacturing firms, due to changes in the sampling frame used for the RD-1 survey. For more information, see http://www.nsf.gov/statistics/s2194/conten3a.htm

[4] This issue is not limited to the service sector. Even in manufacturing, some research effort occurs outside of laboratories, perhaps increasingly so and these activities are harder to measure.

[5] Unfortunately published results from the NSF for the 2008 BRDIS survey (US-NSF, 2010) are not complete enough to report exactly similar numbers for the United States, although it does appear that while innovation rates are lower in services than in manufacturing, in some KIBS they are much higher (e.g., software).

Thinking about important innovations in the service sector during the past few decades, we can see that many of them have been driven by the availability of networked computer and communication technologies: e.g., online reservation, ticketing, and load management systems in airlines, the growth of the logistics industry (Federal Express, DHL, UPS, and so forth); management of inventory systems that span regions or countries; financial innovation of various kinds. Thus past history suggests that innovation in this sector is frequently process-oriented, where changes in process may lead to new and improved products without explicit spending on R&D, and that one useful measure might be the level of investment in new ICT hardware and software. This view is supported by the UK data cited earlier (Hughes and Mina, 2012), where the acquisition of innovation-related machinery, equipment, and software in the service sector ranges anywhere from 30 to 90 percent of innovation expenditure, depending on the sector.

Data from the service sector can also be helpful in informing us about the pricing of certain kinds of research output. In particular, the R&D services sector sells its output on the market to other industrial sectors, as does the computing software sector. Given the difficulty of constructing price deflators for intangible outputs like R&D and software, data on production in these sectors may be useful (see Corrado *et al.*, 2011 for a new attempt to construct an R&D deflator).

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[6] Manufacturing is defined as usual (NACE sector D). The service sector excluding KIBS covers Wholesale trade, Transport, storage & communications, Financial intermediation, Real estate, renting and business activities (excluding those in KIBS). KIBS includes Computer and related activities, R&D services, Architectural and engineering activities, and Technical testing and services.

Non-R&D investment that fosters innovation

In addition to expanding data collection on innovative activity and innovation, it would also be useful to have more information on the inputs to the innovation process that do not fall under the rubric of R&D and hence are not captured systematically by existing surveys in the U.S. These include:

- Acquisition of machinery, equipment and software used to produce new or significantly improved products and processes
- Training for innovative activities - Internal or external training specifically for the development and/or introduction of new or significantly improved products and processes
- Design - to improve or change the shape or appearance of new or significantly improved goods or services

The overall significance of these non-R&D forms of STI investment is difficult to assess, but they are clearly important, at least in some sectors. Hughes and Mina (2012, Figure 3) present data on the distribution of these forms of investment across sectors for the UK. Overall the two largest categories of spending in their figure are internal R&D and capital equipment. The share of innovation expenditure that is internal and external R&D is above 50 per cent only in computing, technical testing and analysis, motion picture and video production, R&D services, and the manufacture of electrical and optical equipment. In many other sectors, including financial intermediation, telecommunications, retail trade and repair, construction, mining, and post & courier activities, the bulk of innovation spending is on the acquisition of machinery, equipment, and software related to innovation. So if we ask what we are missing when we only collect R&D spending data, clearly the most important omission is the purchase of (possibly R&D-intensive) goods from other firms that are used for innovation in the purchasing firms.

As can be seen in Table One, our data related to the accumulation of human capital all relate to education and training in the education sector. But scientists, engineers and other workers also accumulate human capital on the job. Current indicators do include data on scientists and engineers engaged in work-related training, but these data are not connected to the innovation process. This will be particularly important with respect to the introduction and diffusion of new technologies, which may require knowledge and skills that current workers do not possess.

Non-R&D related innovation includes a great deal of design-related activity. In fact, judging from the numbers in Hughes and Mina (2012), design expenditures are relatively more important in several manufacturing industries as in the service sector. One way to try to measure design innovation might be to look at design patenting. At the USPTO, design patent grants were 5.7 per cent of all patent grants in 1963, rising to 8.7 per cent in 2011. Thus in spite of the enormous increase in utility patents during the same period (utility patents grew at 8 per cent per annum during the same period), design patenting grew even faster at 13.7 per cent per annum. From these number we can at least conclude that protecting designs with IPR has increased in importance. Unfortunately, an extensive search of the economics literature has found only one study on the use of design patents and firm performance or innovation.[7] This study, by Bascavusoglu-Moreau and Tether (2011), looks at registered design rights and firm performance (measured as labor productivity) in the UK, finding a positive association prior to 2000, but not after. Unfortunately their analysis is confounded by the fact that there were substantial changes to the benefits and costs of design registration in the UK with the introduction of European community design registration in the early 2000s and by their inability to control for the use of other (related) IP rights. Nevertheless, the study is a useful start to this kind of analysis.

Other issues

Timeliness The usefulness of indicators data is limited by the timeliness with which they are made available. As noted above, data from the 2009 and 2010 BRDIS were not available as of early 2012, although as of the time of this revision (May 2012) they are becoming available in aggregate form. Results from the 2008 Survey of Doctorate Recipients were released only in late 2011. Since these data were collected before the acceleration of the financial crisis in the fall of 2008, as of now we have no information about how the Great Recession affected the job market for S&T degree recipients. Whatever the constraints within the statistical agencies that produce these delays, they greatly limit the value of the information for informing policy.

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[7] There is a literature on design patenting, but it is primarily legal and historical in nature.

Linkages In order to gain meaningful understanding of the underlying processes, it is necessary in many cases to link data from different sources. For example, in order to understand how human capital created at universities contributes to productivity growth of firms, we need to be able to connect the individuals who are granted S&T degrees with their subsequent employers, and the performance of those firms. To go a step further, and analyze the return on the public investment that was made in those degree holders through research and training grants, we need to link the individual degree recipient to the specific grants that supported her education. Making these linkages, and exploiting them to test hypotheses and measure returns, is the province of social science researchers rather than the statistical agencies themselves. But the researchers need the underlying data to be captured in a way that identifies the entities involved in a way that permits subsequent linkage. We have at least one example where a linkage between the Survey of Earned Doctorates and the firms they went to was performed and the researcher was then prevented from publishing work based on this linkage due to NSF concerns about confidentiality. Such a match can be quite informative about firm needs and the supply if highly trained personnel and it ought to be possible to use the data statistically without revealing individual information. The Bureau of the Census has a great deal of experience with this kind of research now, via the federal Research Data Centers.

For looking at the sources and outcomes of federally funded research, the STAR Metrics project, launched by NSF with the cooperation of NIH, DOE and EPA, is an initial effort to capture information about all research grants to universities by these agencies in such a way that the people involved in the research can subsequently be connected to their activities (National Academy of Science, 2011, pp. 72-74).

Measures of knowledge advancement in specific policy-relevant areas The NSF-published indicators do not systematically present data on publication or patent trends in specific areas of public policy interest, such as environment, national security or health. The underlying data exist, however, to prepare such series, based on journal and patent classifications. Hence this is an example of an area where individual researchers, supported by public research funding to the extent the questions are deemed important, can provide the necessary indicator series on the basis of data that are available.

Capital available for financing of technology commercialization The existing indicators provide a wealth of data related to the financing of research. The only data they include on financing of the commercialization stage of innovation is on government programs (e.g. SBIR, ATP), and venture capital funding. This leaves a significant gap with respect to so-called "angel funding," i.e. private funding of startup or other small firms by individuals. A recent survey by the OECD (OECD, 2011) concluded that angel financing is an important source of capital for new and small firms in most countries, but is difficult to quantify because of the heterogeneity of institutions and the consequent difficulty of finding an appropriate target population for data collection.

Exports and imports An important measure of international competitiveness is the trade balance in advanced technology products. But this is difficult to measure when manufacturing is globalized, as the products whose profits accrue to U.S. firms may be manufactured and assembled in more than one country. Ordinarily these firms will use some form of transfer pricing when they move the components from country to country. The NSF S&E Indicators 2010 volume presents a number of high technology trade indicators for the U.S. and the rest of the world that are mostly derived from U.S. Census data. However it is unclear to what extent these data allocate the value addition created by these products correctly, given their multinational origins. The Apple iPod is a notorious example of a product whose market price is considerably in excess of its manufacturing cost (Dedrick *et al.*, 2010). How much of that value creation is allocated to the U.S. trade balance depends heavily on how the prices allocate value added among the various component suppliers and Apple itself.

7

Conclusion

Table 7.1 summarizes the relationship of the existing indicators to the Key Issues and Questions for STI Indicators put forward in the Interim Report. In general, the Table shows that the existing indicators do provide a wealth of information relevant to the key issues, with the possible exception of "Systemic Changes on the Horizon." If one looks more deeply, however, at the specific questions identified in the Table, it is also clear that the indicators, in and of themselves, do not provide answers to the questions posed.

In our view, indicators and other data will never, in and of themselves, provide answers to questions of this kind. The questions posed are, for the most part, research questions. Answering them requires not just data but modeling and analysis. Indicators and data more generally are necessary inputs to the research process that can provide answers to these questions, but they do not provide the answers without that analysis.

It is therefore worthwhile to ask to what extent gaps in the existing data and indicators constitute important barriers to getting the answers we want. Our view is that, for the most part, the important barriers are not gaps in the data. In the previous section, we did identify several gaps and issues with existing indicators. If these could be addressed, it would facilitate better analysis of the important questions. But at a macro level, we do know the answers to many of the important questions. Investment in R&D is a major driver of productivity growth, and the rate of return to both private and public R&D investments is relatively high. Despite this relationship being clear on average, innovation is a very risky process, so that there is a lot of variance in the results of all innovation efforts. Growth in human capital is a key (perhaps the key) determinant of growth in income, both for individuals and for society as a whole.

Note that all of these questions for which we have pretty good answers are questions about how the world works, not the normative questions of what we should do to improve STI outcomes. These normative questions are much harder to answer. For the most part, the reason why these normative questions are hard to answer has little to do with STI indicators. First, they often involve value judgments about the *relative* value to society of different desirable outcomes, such as better health and a cleaner environment. In addition, some of the most important policy questions relate to the relative effectiveness or efficiency of different policy instruments, e.g. R&D tax credits versus public R&D or grants to universities versus funding government R&D labs. These questions are more answerable in principle than the pure value questions, but the answers require careful, systematic research rather than generic data collection. They could be answered if the Congress and the agencies were interested in systematic program evaluation, and were willing to allocate money for such evaluation. But they will not be answered by different STI indicators.

There is one category of normative questions that does, in principle, relate to indicators, and that is the allocation of public resources across different disciplines or areas of research. Although this contains an element of pure value judgment, it also clearly depends on the rate of return to research in different areas, which could theoretically be observed with ideal indicators. But in reality the incommensurable nature of research outputs in different areas, combined with the highly stochastic nature of research success makes it unlikely that better data is going to provide convincing measures of the differences in rates of return across fields.

Even if better STI Indicators will not provide answers to the "big" questions, there remain important improvements (some already underway) that the Panel can encourage. As discussed in more detail in the previous section, the most important of these include:

- Better coverage of the service sector in R&D and innovation surveys;
- Implementation of innovation surveys, with eventual expansion to include measures of cost savings associated with process innovation;
- Collection of information on investments in equipment and software in support of innovation;
- Collection of information on design efforts;
- Collection of information on training of employees for diffusion and adoption of innovations;
- More timely publication of indicators and availability of micro data to researchers;
- Collection and maintenance of data by grant-making agencies on individual grants and researchers in such a way that they can be linked to other data sources.

Finally, we note again that not all data collection and indicator publication has to be undertaken by the government. Particularly when it comes to experimental or innovative use of passive data collection, individual researchers (typically funded by public research grants) can in many cases collect and publish the data. So long as adequate research funding for such efforts is maintained, this is likely to provide for more extensive and ultimately successful development of new indicators than mandating collection of specific data by the government agencies.[1] Over time, if particular measures prove useful, it would then be possible to assimilate them into the arsenal of officially collected and published statistics.

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[1] Such research funding should also come with the clear mandate to make the data available for subsequent researchers so that the data can be tested and its utility for other uses explored.

Table 7.1: Key Issues and Questions For STI Indicators.

Issue	Current Indicators	Possible Additional Indicators
Growth, Productivity and Jobs What is the contribution of science, technology, and innovation (STI) activity to productivity, employment and growth? What is the relative importance of technological innovation versus non-technological innovation for economic growth? Is the United States falling behind with respect to innovation and what are the effects on socioeconomic outcomes?	Value-added Exports International royalties Foreign direct investment	Innovation revenues Innovation cost savings Service sector innovation
STI Activities What are the drivers of innovation? How influential is R&D for innovation and growth (by sector)? What would constitute a "balance" between the biological and physical sciences? On what basis could that be determined? Does biological science depend on physical science for advancement? How important are the following for advancing innovation: small businesses, large businesses, strategic alliances, technology transfer between universities and firms, academic researchers, government labs and procurement activities, and nonprofit organizations? What are the emerging innovative sectors and what is unique about them?	R&D expenditures by sector and performing organization Degrees Postdocs Education spending Test scores Technology alliances	Capital investment for innovation Design investment

Table 7.1: *continued*

Issue	Current Indicators	Possible Additional Indicators
STI Talent How much knowledge capital does the United States have? How many people, possessing what kind of skills, are needed to achieve a robust STI system? What additional sources of "talent" can best be tapped – especially among immigrants, women, and minorities? How many science and engineering doctorate holders took nontraditional pathways into the science, technology, engineering and mathematics (STEM) workforce? Did this vary by race/ethnicity, gender or the existence of a disability? How important are community colleges in developing human resources for STEM talent? Is the U.S. falling behind in STEM workers? What fields other than science, technology, engineering, and mathematics are important for advances in STI?	Enrollment Degrees Occupations (by country of origin)	Training for innovation adoption and diffusion
Private Investment, Government Investment and Procurement What impact does federal research spending have on innovation and economic health, and over what time frame? How large should the federal research budget be? How should policy makers decide where to put additional research dollars or reallocate existing funding streams – information and communications technology, biotechnology, physical science, nanotechnology, environmental technology, social science, etc.? Does government investment crowd out or energize private investment STI activities? What is the role of entrepreneurship in driving innovation?	Public expenditures broken down in various ways	

Table 7.1: *continued*

Issue	Current Indicators	Possible Additional Indicators
Institutions, Networks and Regulations What impacts are federal research programs having on entrepreneurial activities in science and engineering sectors? Where are the key gaps in the transfer of scientific and technological knowledge that undercut the performance of the STI system? Where is the supposed "valley of death" in innovation? In which industries is the valley of death most prevalent? What part of the process is underfunded for specific sectors? What is the nature and impact of intellectual property protection on scientific and innovation outputs?	Contract R&D ATP, SBIR, STTR Mfg. extension	Birth and death rates for innovative startups Survey evidence on abandoned projects (as in CIS)
Global STI Activities and Outcomes: What can we learn from other countries and what are other countries learning from us? In what technological areas are other countries accelerating? What impact does the international flow of STI have on U.S. economic performance? What is the relative cost of innovation inputs in the U.S. versus other countries? Where are multinational corporations sourcing R&D? What are the institutional differences that affect innovation activities among nations and how are they changing?	International Co-authoring Trade in R&D Royalties Foreign direct investment Foreign enrollment	Improved collection of cross-border R&D investment

Table 7.1: *continued*

Issue	Current Indicators	Possible Additional Indicators
Subnational STI Activities and Outcomes How does innovation activity in a given firm at a given place contribute to that firm's productivity, employment and growth, and perhaps also to these characteristics in the surrounding area? How are those innovation supply chains working within a state? Are firms principally outsourcing new knowledge from customers or from universities?	R&D data Patent data Student scores S&E doctorate holders	Innovation survey data on sources of knowledge
Systemic Changes on the Horizon How will demographic shifts affect the STEM workforce, nationally and internationally? Will it shift the locus of the most highly productive regions? Will global financial crises slow innovation activities or merely shift the locus of activities? When will emerging economies be integrated into the global ecosystem of innovation and what impact will that have on the system? How are public views of science and technology changing over time?	Consumer attitudes	See above

References

Abramovitz, M. (1956). "Resource and output trends in the United States since 1870". *American Economic Review*. 46(2): 5–23.

Acemoglu, D., P. Aghion, L. Bursztyn, and D. Hemous (2012). "The environment and directed technical change". *American Economic Review*. 102(1): 131–166.

Acs, Z. J. and D. B. Audretsch (1990). *Innovation and Small Firms*. Cambridge, MA: MIT Press.

Allman, K., J. Edler, L. Georghiou, B. Jones, I. Miles, O. Omidvar, R. Ramlogan, and J. Rigby (2011). *Measuring Wider Framework Conditions for Successful Innovation: A System's Review of UK and International Innovation Data*. London, UK: NESTA Report. URL: https://www.nesta.org.uk/sites/default/files/measuring_wider_framework.pdf.

Balconi, M., S. Brusoni, and L. Orsenigo (2010). "In defence of the linear model: an essay". *Research Policy*. 39: 1–13.

Bascavusoglu-Moreau, E. and B. S. Tether (2011). "Registered designs and business performance - exploring the link". In: *Design Economics*. Chapter 2. London, UK: UK Intellectual Property Office. URL: http://www.ipo.gov.uk/pro-ipresearch/ipresearch-right/ipresearch-right-design.htm.

Belitz, H., M. Clemens, C. von Hirschhausen, J. Schmidt-Ehmcke, A. Werwatz, and P. Zloczysti (2011). "An Indicator for National Systems of Innovation - Methodology and Application to 17 Industrialized Countries". DIW-Berlin Discussion Paper No. 1129.

Carson, C. S. (1994). *A Satellite Account for Research and Development.* November: Survey of Current Business. URL: http://www.bea.gov/scb/account_articles/national/1194od/maintext.htm.

Corrado, C., P. Goodridge, and J. Haskel (2011). "Constructing a Price Deflator for R&D: Calculating the Price of Knowledge Investments as a Residual". Working Paper No. EPWP#11-03. New York, NY: The Conference Board.

David, P. A. (2012). "Introductory comments on Innovation Incentives, Institutions and Economic Growth". In: *The Rate and Direction of Inventive Activity Revisited.* Ed. by J. Lerner and S. Stern. University of Chicago Press.

David, P. A., B. H. Hall, L. Soete, and A. van Zon (2011). *Global Warming and the S&T Research Policy Challenge: Neither the Ghetto nor the Moon.* draft: Stanford University and University of Maastricht.

Dedrick, J., K. L. Kraemer, and G. Linden (2010). "Who profits from innovation in global value chains?: a study of the Ipod and Notebook PCs". *Industrial and Corporate Change.* 19(1): 81–116.

European Union (2012a). *Innovation Scoreboard 2011.* URL: http://www.proinno-europe.eu/metrics.

European Union (2012b). *Key research & innovation indicators and economic analysis to support policy making.* URL: http://ec.europa.eu/research/era/facts/figures/key_figures_en.htm.

Fraumeni, B. M. and S. Okubo (2005). "R&D in the National Income and Product Accounts: A First Look at Its Effect on GDP". In: *Measuring Capital in the New Economy.* Ed. by C. Corrado, J. Haltiwanger, and D. Sichel. NBER conference volume, pages 275-322.

Griliches, Z. (1986). "Data Issues in Econometrics". In: *Handbook of Econometrics.* Vol. III, Chapter 21. Ed. by Z. Griliches and M. Intriligator. Amsterdam: North-Holland.

Hall, B. H. (2005). "Measuring the Returns to R&D: The Depreciation Problem". *Annales d'Economie et de Statistique*. 79/80: 341–381.

Hall, B. H. (2011). "Innovation and productivity". *Nordic Economic Policy Review*. 2: 167–204.

Hall, B. H., C. Helmers, M. Rogers, and V. Sena (2013). "The importance (or not) of patents to UK firms". *Oxford Economic Papers*. 65(3): 603–629.

Hall, B. H., J. Mairesse, and P. Mohnen (2010). "Measuring the Returns to R&D". In: *Handbook of the Economics of Innovation*, Volume II, pages 1032-1080. Amsterdam and New York: Elsevier.

Hughes, A. and A. Mina (2012). *The UK R&D Landscape*. CIHE and UK IRC Report for the Enhancing Value Task Force. URL: http://www.ncub.co.uk/rdlandscape.

Jankowski, J. (2012). "Update on the Business R&D and Innovation Survey". Presentation to the Fourth Meeting of the Panel on Developing STI Indicators for the Future, Washingon, DC, February 7.

Jankowski, J. (2013). *Measuring Innovation with Official Statistics*. In: *Handbook on the Theory and Practice of Program Evaluation*. Ed. by A. N. Link and N. Vonortas. Cheltenham, UK: Edward Elgar.

Jorgenson, D. W. and Z. Griliches (1967). "The explanation of productivity change". *Review of Economic Studies*. 34(3): 249–83.

Kline, S. J. and N. Rosenberg (1986). "An overview on innovation". In: *The Positive Sum Strategy*. Pages 275-305. Ed. by R. Landau and N. Rosenberg. Washington, DC: National Academy Press.

Mairesse, J. and P. Mohnen (2010). "Using innovation surveys for econometric analysis". In: *Handbook of the Economics of Innovation*. Volume II, pages 1129-1155. Ed. by B. H. Hall and N. Rosenberg. Amsterdam and New York: Elsevier.

Mowery, D. C. (2010). "Military R&D and innovation". In: *Handbook of the Economics of Innovation*. Volume II, pages 1220-1258. Ed. by B. H. Hall and N. Rosenberg. Amsterdam and New York: Elsevier.

National Academy of Science (2011). *Measuring the Impacts of Federal Investments in Research: A Workshop Summary* (Report of the Committee on Measuring Economic and Other Returns on Federal Research Investments, Steve Olson and Stephen Merrill, Rapporteurs). Washington, DC: The National Academies Press.

Nelson, R. R., ed. (1993). *National Innovation Systems: A Comparative Analysis*. Oxford University Press.

OECD (2011). *Financing High-Growth Firms: The Role of Angel Investors*. Technology, Industry Directorate's Committee for Industry, Innovation, and Entrepreneurship (CIIE) High-Growth Financing Project.

Peters, B. (2006). "Productivity effects of innovation activities". In: *Innovation and Firm Performance: An Empirical Investigation for German Firms*. University of Würzburg: PhD thesis. Chapter 4.

Popp, D., R. G. Newell, and A. B. Jaffe (2010). "Energy, the environment, and technological change". In: *Handbook of the Economics of Innovation*. Volume II, pages 874-930. Ed. by B. H. Hall and N. Rosenberg. Amsterdam and New York: Elsevier.

Rogoff, K. (2017). "The US is exporting obesity". URL: https://www.theguardian.com/business/2017/dec/04/us-obesity-trump-processed-foods-health.

Rosenberg, N. (1982). *Inside the Black Box*. Cambridge University Press: Cambridge.

Soete, L. (2012). "Maastricht reflections on innovation". Working Paper No. 2012-001. Maastricht, The Netherlands: UNU-MERIT.

Solow, R. M. (1957). "Technical change and the aggregate production function". *Review of Economics and Statistics*. 39(3): 312–320.

Tanaka, N., M. Glaude, and F. Gault (2005). *Oslo Manual: Guidelines for collecting and interpreting innovation data, third edition*. Paris: OECD/OCDE and Eurostat.

US Government (2011). *Economic Report of the President*. Council of Economic Advisors. Washington, DC: Government Printing Office.

US Government (2012). *Health Care Satellite Account*. Bureau of Economic Analysis. URL: http://www.bea.gov/national/health_care_satellite_account.htm.

US Government and National Science Foundation (2009). *Business R&D and Innovation Survey.* URL: http://www.nsf.gov/statistics/srvyindustry/about/brdis/.

US Government and National Science Foundation (2010). "NSF releases new statistics on business innovation". *SRS Info Brief NSF.* (October): 11–300.

Wessner, C. W., ed. (2009). *An Assessment of the SBIR Program at the Department of Defense.* Washington, DC: National Academies Press.

Author Biographies

Bronwyn Hall is Professor of Economics Emerita at the University of California at Berkeley, Visiting Professor at MPI-Munich, and Research Associate at the NBER and IFS-London. She has published numerous articles on the economics and econometrics of technical change and innovation and is the editor of the Handbook of the Economics of Innovation in the Elsevier series. Her research includes analysis of the use of intellectual property systems in developed and developing countries, the valuation of intangible (knowledge) assets, comparative firm level R&D investment and innovation studies, measuring the returns to R&D and innovation, and analysis of technology policies such as R&D subsidies and tax incentives. She has made substantial contributions to applied economic research via the creation of software for econometric estimation and of firm level datasets for the study of innovation, including the widely used NBER dataset for U.S. patents.

Adam B. Jaffe is Senior Research Associate with Motu Economic and Public Policy Research in Wellington, New Zealand and Adjunct Professor with Queensland University of Technology in Brisbane, Australia. He served Motu as Director and Senior Fellow 2013-2017. He was previously the Fred C. Hecht Professor in Economics, Chair of Economics and Dean of the Faculty of Arts and Sciences at Brandeis University in Waltham, Massachusetts, U.S.A. Jaffe is the author of two books – *Patents, Citations and Innovations: A Window on the Knowledge Economy* (with Manuel Trajtenberg, 2002); and *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress and What to Do About It* (with Josh Lerner, 2004). He is also the editor (with Ben Jones, 2015) of *The Changing Frontier: Rethinking Science and Innovation Policy.* In 2017, his paper with Richard Newell and Rob Stavins, "The Induced Innovation Hypothesis and Energy-Saving Technological Change" (1999) won the Association of Environmental and Resource Economists Award for Publication of Enduring Quality. Jaffe's research focuses on technological innovation and technology diffusion, particularly as it affects environmental and energy technologies, and on science and innovation policy.